JURISDICTION OF THE MEDICAL ETHICS COMMITTEES
PRISTOJNOSTI KOMISIJ ZA MEDICINSKO ETIKO

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Editorial

ABSTRACT

Ethical principles of assessing medical research are to the greatest extent defined by the Nuremberg Code, the Declarations of Geneva and Helsinki, and the Oviedo Convention. Pursuant to their directives various national Medical Ethics Committees (MECs) were established which assess the ethics of research according to the risk and benefit ratio of the persons involved. Following the example of other countries, medical ethics committees eventually appeared also in hospitals and some medical and educational institutions around Slovenia. Due to an increased number of ethical challenges, it is of great importance to define the jurisdiction of the Slovenian MECs in order to ensure their coordinated operation. Exclusive jurisdiction of the national MEC includes multi-centre and multi-national research, drug research (phases 1–3), high-risk research and research related to doctoral theses. The jurisdiction of the sectoral MECs includes testing the conditions for research, monitoring the execution and overviewing the final reports. A more significant jurisdiction of the sectoral MEC is preserving an ethical environment in their institutions. A network of Slovenian MECs is to be organised in the form of a jurisdiction pyramid where each member has its own obligations and responsibilities and plays an important role in relation to the entire structure.

Keywords:
medical ethics committees, jurisdiction

IZVLEČEK

Etična načela presojanja zdravstvenih raziskav v največji meri določajo Nürnberški kodeks, Ženevska in Helsinška deklaracija ter Oviedska konvencija. Po njihovih usmeritvah so po državah ustanovili Komisije za medicinsko etiko (KME), ki etičnost raziskav presojajo predvsem po tveganjih in koristih vanje vključenih oseb. Kot drugod so se sčasoma tudi v Sloveniji pojavile komisije pri bolnišnicah in nekaterih zdravstveno-izobraževalnih ustanovah. Ker je etičnih izzivov vse več, je za usklajenost delovanja slovenskih KME potrebno določiti njihove pristojnosti. V izključno pristojnost državne KME sodijo multicentrične in večnacionalne raziskave, raziskave zdravil v fazi 1-3, raziskave z večjim tveganjem in raziskave, povezane z doktorskimi nalogami. Pristojnost področnih KME naj bi bilo na področju raziskav preverjanje pogojev zanje, spremljanje njihovega poteka in pregled zaključnih poročil. Veliko bolj pomembna pristojnost področnih KME je vzdrževanje etične kulture v njihovih ustanovah. Mreža slovenskih KME naj bi bila organizirana v obliki pristojnostne piramide, v kateri ima vsak člen s svojimi dolžnostmi in odgovornostmi pomen tudi za celoto.

Ključne besede:
komisije za medicinsko etiko, pristojnosti

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1 DEVELOPMENT OF MEDICAL ETHICS COMMITTEES

After World War II Nazi doctors were being judged at Nuremberg trials for carrying out all sorts of research on prisoners in concentration camps in any way they wanted it. At that point it became obvious that doctors and their research should be monitored. The Nuremberg panel of judges suggested 10 principles of research in healthcare, also known as the Nuremberg Code (1), which defined the moral principles of medical research, prohibited any sort of violence related to research and introduced the concept of informed consent. In 1948, under the influence of the Code, the General Assembly of the World Medical Association adopted the Declaration of Geneva (2) in which they stated 11 principles defining the medical ethics. In 1964, the same Association adopted also the Declaration of Helsinki on medical research (3) which demands experienced researchers, respect of the set protocols and ethical supervision by a competent committee that carefully assesses the risks and benefits of the persons involved. The development of biomedicine was accompanied by updating the ethical provisions with the Oviedo Convention (4). Today the research is also influenced by other conventions and declarations, principles of good clinical practice and quality standards.

After the Declaration of Helsinki was adopted, the countries started appointing medical ethics committees (MECs) and introducing ethical assessment into research. One of the first ones was the Slovenian committee for assessing the ethical appropriateness of doctoral theses established in 1966 at the initiative of Prof. Dr. Janez Milčinski. Over the years the number of national committees increased. With the development of bioethics the fields of assessment expanded, and many MECs appeared in hospitals, some also in medical and educational institutions. This was the case also in Slovenia where hospital committees for ethical consulting and monitoring were established, as well as various committees at medical schools and faculties, some of them also wishing to take over the ethical assessment of medical research.

2 NEED TO REORGANISE MECs IN SLOVENIA

As the jurisdiction of particular MECs in Slovenia is not officially determined, the situation concerning this field is very unstable. Plenty of research is carried out, the national MEC receives more than 70 applications per month, among which also diploma theses. Due to the increased workload and the lack of administrative support, the MEC suffers a reputation of not being responsive enough. The committees do not cooperate enough and it would be necessary to implement ethical training for its members. The gender ratio of its members is unequal and the field of nursing care is being neglected. The objective of the national MEC is to create an environment in which the Slovenian medical and ethical community would follow the example of well-established conditions in developed European countries, where Slovenian healthcare and society definitely belong according to their progress and potential. The aim of some hospital and other MECs to take over also the assessment of ethical appropriateness of suggested research increases the possibility of an occurring conflict of interests. By reorganising the national MEC, the responsibilities of both the national and sectoral MECs should be determined taking into account the development of bioethics in the past 20 years. In 1998, the responsibilities were proposed by Prof. Dr. Jože Trontelj in collaboration with the presidents of the sectoral MECs (5), but they were never processed any further. Everything they proposed still holds valid today, however some fields need to be amended in the light of today's circumstances and relations.

3 JURISDICTION, OBLIGATIONS AND RESPONSIBILITIES OF THE MEDICAL ETHICS COMMITTEES

Each jurisdiction is also in the case of MEC related to the corresponding obligations and responsibilities.

In the case of the national MEC, the authorities that fall within its exclusive jurisdiction are all types of research that is carried out in different institutions or countries, all clinical drug research in phases 1 – 3, high-risk research, research that is funded by public money, and research that is part of a doctoral thesis. For all publications of research results in professional literature, the date and the number of the positive ethical assessment of the national MEC should be provided to the editorial office.

The national MEC also assesses the research that can otherwise be assessed by the sectoral MEC, but has led to a conflict of interests or an insufficient unanimity in the assessments. In that case the national MEC is entitled to solve the appeals to the decisions of the sectoral MECs.
The national MEC also decides on matters of medical ethics on a national level, as well as carries out other tasks set out in the Rules of its operation.

In the field of research the sectoral or hospital MECs verify if the patients or persons involved in a particular research were notified of the intent and risk concerning the research, and if they are aware of their rights. They assess the qualifications of the researcher, as well as the adequacy of equipment and the number of patients or persons involved. They monitor if the research is carried out according to the initial plan, if potential professional or ethical complications may occur, if a change in protocol occurred, and in the event of occurring complications,

the MECs decide if the research has to be interrupted or terminated. When the research is completed, the sectoral MECs revise the final report.

A more important jurisdiction of the hospital MECs is to monitor and promote an ethical environment in healthcare institutions (6), which can be demonstrated in the realisation of the patients' rights and their active role in the processes of medical treatment, in respecting the moral principle of not causing harm, as well as in carrying out its services with quality and justice. In the framework of the stated ethical fields, the hospital MECs make sure the patients consent to the treatment and take part in it after they have been informed in a comprehensible way about its intent, benefits and risks. They defend the services and procedures that would benefit the patients the most or are the most appropriate for them. They also identify conflicts between employees, which could lead to ethically questionable behaviour of doctors and other medical staff, they monitor the ethical aspects in carrying out "good practice" and in breaching the professional doctrine, including the ethical aspects of complications occurring in the treatment process. If needed, they suggest ethical improvements and measures for a better transparency of the procedures, services and the decision-making process. While new diagnostic and therapeutic methods are being introduced, they pay attention to the related ethical circumstances. If needed, they discuss and consult regarding the appropriateness of introducing or suspending and continuing or terminating the treatment. They also advise various ad hoc committees (in cases of brain death, transplantation etc.) and influence the ethical education of trainee specialists, as well as doctors and other personnel.

4 CONCLUSION

While discussing the jurisdiction of particular MECs, the starting point cannot be their competitiveness, but cooperation. The network of Slovenian MECs should be organised in the form of a jurisdiction pyramid where each member plays a significant role in relation to the entire structure. Slovenian healthcare faces a lot of ethical challenges, many of them still unsolved despite numerous MECs. The jurisdiction of all MECs is to assess in a just, responsible and impartial manner not only the research, but also the conditions in healthcare institutions and in healthcare in general, with the aim to put the benefit of the patient first. Such standpoint should also be supported by the health politics and the management of healthcare institutions. The medical ethics should have a positive effect also on the Slovenian society which could use some encouragement after all the media and political negativity.

CONFLICTS OF INTEREST

The author reports no conflicts of interest.

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ETHICAL APPROVAL

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RUNNING INJURIES IN THE PARTICIPANTS OF LJUBLJANA MARATHON
TEKAŠKE POŠKODBE UDELEŽENCEV LJUBLJANSKEGA MARATONA

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ABSTRACT

Introduction. The aim of our study was to determine the self-reported incidence and prevalence of running-related injuries among participants of the 18th Ljubljana Marathon, and to identify risk factors for their occurrence.

Methods. A customized questionnaire was distributed over registration. Independent samples of t-test and chi-square test were used to calculate the differences in risk factors occurrence in the injured and non-injured group. Factors which appeared significantly more frequently in the injured group were included further into multiple logistic regression analysis.

Results. The reported lifetime running injury (absence >2 weeks) incidence was: 46% none, 47% rarely, 4% occasionally, and 2% often. Most commonly injured body regions were: knee (30%), ankle and Achilles' tendon (24%), foot (15%), and calf (12%). Male gender, running history of 1-3 years, and history of previous injuries were risk factors for life-time running injury. In the season preceding the event, 65% of participants had not experienced any running injuries, 19% of them reported minor problems (max 2 weeks absenteeism), but 10% and 7% suffered from moderate (absence 3-4 weeks) or major (more than 4 weeks pause) injuries. BMI was identified as the solely risk factor.

Conclusions. This self-reported study revealed a 53% lifetime prevalence of running-related injuries, with the predominate involvement of knee, ankle and Achilles' tendon. One out of three recreational runners experienced at least one minor running injury per season. It seems that male gender, short running experience, previous injury, and BMI do increase the probability for running-related injuries.

Keywords:
sports, running, marathons, injuries, prevalence, incidence, risk factors

IZVLEČEK

***Izhodišča**. V pretekli dekadi se je število rekreativnih udeležencev teka na dolge proge v Sloveniji pomembno zvišalo in znaša 40.000 tekačev, kar predstavlja približno 2 % prebivalstva. Leta 2013 se je 18. Ljubljanskega maratona udeležilo skoraj 20.000 tekačev. Več kot 1400 jih je nastopilo na maratonu, 6500 jih je teklo polmaraton, ostali so se udeležili teka na 10 km. Namen naše raziskave je bil določiti incidenco in prevalenco prijavljenih tekaških poškodb udeležencev 18. Ljubljanskega maratona in opredeliti dejavnike tveganja za njihov nastanek.*

***Metode**. Ob prijavi smo 14.176 udeležencem po elektronski pošti poslali povezavo do spletnega vprašalnika, ki je vseboval splošne podatke, tekaško zgodovino in življenjsko/sezonsko prevalenco/incidenco tekaških poškodb. Sodelovanje v raziskavi je bilo prostovoljno in anonimno. Odgovori so predstavljeni z ustreznimi merami opisne statistike. Statistično značilnost razlik v dejavnikih tveganja med poškodovanimi in nepoškodovanimi udeleženci smo vrednotili s Studentovim t-testom oziroma testom hi-kvadrat. Za dejavnike, ki so se izkazali za značilno pomembne v bivariatni analizi, smo v modelu multiple logistične regresije določali njihovo neodvisno napovedno vrednost za tekaško poškodbo.*

***Rezultati**. V raziskavi je sodelovalo 340 žensk in 357 moških. Njihova povprečna starost je bila 42 let, povprečen ITM je bil 23,1 kg/m2. Glede na pretečeno razdaljo je bila razporeditev naslednja: maraton 132, polmaraton 412 in tek na 10 km 153 udeležencev. Življenjska incidenca tekaških poškodb (odsotnost s teka 2 tedna ali več) je bila naslednja: 322 (46 %) nikoli, 328 (47 %) redko, 31 (4 %) občasno in 16 (2 %) pogosto. Najpogosteje poškodovani telesni deli so bili: koleno (30 %), gleženj in Ahilova tetiva (24 %), stopalo (15 %) in meča (12 %). Kot dejavniki tveganja za življenjsko tekaško poškodbo so bili opredeljeni moški spol, ukvarjanje s tekom 1-3 leta in zgodovina poškodb. V sezoni pred dogodkom 65 % udeležencev ni imelo tekaške poškodbe, 19 % jih je prijavilo manjšo težavo (največ 2 tedna odsotnosti s teka), 10 % jih je utrpelo zmerno poškodbo (odsotnost s teka 3-4 tedne) in 7 % večjo (več kot 4 tedne premora). ITM je bil edini ugotovljeni dejavnik tveganja.*

***Zaključki**. Raziskava prijavljenih poškodb udeležencev 18. Ljubljanskega maratona je pokazala 53-odstotno življenjsko incidenco tekaških poškodb; prevladujejo poškodbe kolena ter gležnja in Ahilove tetive. Eden od treh rekreativnih tekačev utrpi vsaj eno manjšo tekaško poškodbo na sezono. Dejavniki, ki povečajo tveganje za nastanek tekaške poškodbe, so moški spol, kratkotrajno ukvarjanje s tekom, pretekla poškodba in ITM.*

Ključne besede:
šport, tek, maratoni, poškodbe, prevalenca, incidenca, dejavniki tveganja

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1 INTRODUCTION

The public perception of running as a health promoting activity is important in many respects, and distance runners are now accepted as a significant leisure interest group in society. Exercise has increasingly been seen as an important facet of a 'healthy society', with leisure and sport providing many of the activities through which it is hoped this can be achieved (1). Moreover, endurance running has shown to be effective in providing substantial beneficial effects on body mass, body fat, resting heart rate and cholesterol levels in physically inactive individuals, making it an important asset for public health programs (2). The result is an increased popularity of marathon and long distance running in the last decade that produced around 40,000 competitive runners across Slovenia, which represents 2% of the population (3). The 18th Ljubljana Marathon in 2013, recorded almost 20,000 participants. More than 1,400 participants attended the 42-km run, 6,500 participated in half-marathon, and the rest ran over 10 km distance. The increasing amount of runners willing to have a positive impact on their health is followed by an increased incidence of running-related injuries (RRI), ranging from 18.2% to 92.4%, and prevalence ranging from 6.8 to 59 injuries per 1,000 hours of training (4). At any given time, 25% of long distance runners are injured, and about a half experience an injury that stops their activity for a period during a year (5). Although some injuries are traumatic, most are due to overuse. The definition of an ''injury'' varies in the literature. However, the most common definition of RRI is: a musculoskeletal ailment that is attributed to running and that causes a restriction of running speed, distance, duration, or frequency for at least 1 week (6). The aetiology of RRI is usually related to overuse with repeated musculoskeletal microtrauma, and can be attributed to several risk factors described in the literature. Each one of them is affected by personal characteristics of the runner (anatomical and biomechanical factors), training errors (such as training volume, weekly distance), and running experience (4).

The aim of our study was to evaluate the frequency of RRI and determine the self-reported incidence and prevalence of those injuries among participants of the 18th Ljubljana Marathon. We also tried to discriminate risk factors for the occurrence of RRI and contribute to better prevention in this study population.

2 METHODS

The study was designed as a retrospective cohort study based on a customized questionnaire, distributed over registration emails to 14,176 participants of the 18th Ljubljana Marathon (held on 27 October 2013). Participation in the study was voluntarily and anonymous. Only the runners' race numbers were tracked. The data was collected prior to the race and advertised during registration. The customized questionnaire in Slovenian language contained general data, running history, running distance per week, previous participation at an official event, type of training for the event, regions of RRI, other sports participation, barefoot running, and life/season prevalence/incidence of RRI. RRI was defined as a cause of absence from running for 2 weeks or more due to an injury that was caused with running only. Questions were specifically designed to target RRI risk factors reported elsewhere (4, 7, 8). The questionnaire had to be filled completely to be submitted. All answers were received electronically and screened. Participants who did not appear on the race, or the ones not finishing the run, were excluded from the data analysis.

Simple descriptive statistics was used to present the characteristics of the study population. Two different outcomes were observed in regard to running related injuries, namely: runners injured during last season (incidence), and runners with a life-time injury (prevalence). We used gender, age, BMI, running experience, running distance per week, other sports participation, barefoot running, types of preparation for the marathon, official event experience, and history of previous running injuries as explanatory variables. The data is presented as mean±SD. Independent samples of t-test and chi-square test were used to calculate the differences in potential risk factors occurrence in the injured and non-injured group. Factors which appeared significantly more frequently in the injured than in non-injured group were included further into multiple logistic regression analysis with the aim to confirm or reject their role as independent risk factors for running-related injuries. All variables were included simultaneously, using the ENTER method. P value of less than 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics version 24.

3 RESULTS

Out of 14.176 distributed questionnaires, 814 were returned (response rate= 5.7%). 213 runners did not appear and 4 did not finish the race, and were removed from the research. At the end, 697 were eligible for further analysis.

There were 340 (48.8%) females and 357 (51.2%) males participating in the study. Their average age was 42±11 years, and their average body mass index (BMI) was 23.1±2.6 kg/m^2. Runners' distribution according to the running distance at the event was: full marathon 132 (18.9%), half-marathon 412 (60.1%), and 10 km run 153 (21%) participants. The participants reported lifetime

running injury (absence more than 2 weeks) prevalence as following: 322 (46%) none, 328 (47%) rarely, 31 (4%) occasionally, and 16 (2%) often. Most commonly injured body regions were: knee (30%), ankle and Achilles' tendon (24%), foot (15%), and calf (12%). Incidence was observed in the season preceding the 18th Ljubljana Marathon event. 452 (65%) participants had not experienced any running injuries, 131 (19%) of them reported minor problems (max 2 weeks absenteeism), but 66 (10%) and 48 (7%) participants suffered from moderate (absence 3-4 weeks) or major (more than 4 weeks healing pause) running-related injuries. The results are presented in the Table 1.

Table 1. Baseline characteristics of runners in a study group at 18th Ljubljana Marathon (N=697).

Variable	Analyzed group (n=697)
Gender	
Females vs. Males	340 (49%) / 357 (51%)
Age (mean±SD)	42±11 years (14 to 68 years)
10-19 years	9 (1%)
20-29 years	94 (13%)
30-39 years	184 (26%)
40-49 years	247 (35%)
50-59 years	121 (17%)
60-69 years	42 (6%)
BMI (mean±SD)	23.1±2.6 kg/m^2 (16.9 to 38.1 kg/m^2)
<25	545 (78%)
≥25	152 (22%)
Running distance at the 18th Ljubljana Marathon	
Full marathon	132 (19%)
Half-marathon	412 (60%)
10 km	143 (21%)
Life-time running injury prevalence (more than 2 week absence)	
None	322 (46%)
Rarely	328 (47%)
Occasionally	31 (4%)
Often	16 (2%)
Running injury body regions	30% knee / 24% ankle and Achilles' / 15% foot / 12% lower leg / 9% thigh / 8% lower back / 6% hip / 2% pelvis / 1% shoulder / 1% neck / 1% chest
Previous season running injury incidence	
None	452 (65%)
Minor (2 week absence)	131 (19%)
Moderate (3-4 weeks absence)	66 (10%)
Severe (more than 4 week absence)	48 (7%)
Running experience	
Less than 1 year	52 (8%)
1-3 years	213 (30%)
4-10 years	293 (42%)
More than 10 years	139 (20%)
Running distance per week	
Less than 10 km	46 (7%)
11 to 20 km	167 (24%)
21 to 30 km	237 (34%)
31 to 50 km	170 (24%)
More than 50 km	77 (11%)
Other sport activities participation	
Yes vs. No	606 (87%) / 91 (13%)
Previous injury	
Yes vs. No	387 (56%) / 310 (44%)
Barefoot running	
Yes vs. No	89 (13%) / 608 (87%)

We compared two group of runners: one with no life-time RRI and the other with occasional and recurrent injuries. A multiple regression logistic analysis revealed that male gender (p<0.01, ß=0.479), running experience of 1 to 3 years (p<0.01 ß=0.348), and personal history of previous injuries (p<0.01, ß=1.78) were risk factors for life-time RRI. It also showed that higher age was a risk factor for lower leg life-time RRI (p<0.01, ß=0.947), and running distance of 21-30 km (p<0.05, ß=0.453) and 31-50 km per week (p<0.05, ß=0.48) were risk factors for foot lifetime RRI. Barefoot running was also considered a statistically significant risk factor for lower leg life-time RRI (p<0.05, ß=0.523). On the contrary, BMI, running experience of 4 years or more, and other sports participation were not related to lifetime running injuries (Table 2).

In the season preceding the 18th Ljubljana Marathon event, 452 (65%) participants had not experienced any running injury, 131 (19%) of them reported minor problems (max 2 weeks absenteeism), but 66 (10%) and 48 (7%) participants suffered from moderate (absence 3-4 weeks) or major (more than 4 weeks healing break) running-related injuries. BMI was the only risk factor for one-season running period incidence (increase in one point increases the risk for injury for 5.7%). Furthermore, runners that were overweight or obese had significantly more injures than runners with a BMI of less than 25 kg/m^2 (p<0.05). Other factors, such as gender, age, personal running experience, running distance per week, previous participation at a official event, type of training for the event, other sports participation, and barefoot running did not represent a one-season risk factor in our study group. Details are presented in Table 3.

Table 2. Risk factors for running related injuries incidence among participants of 18th Ljubljana Marathon (N=697).

Variable	No injuries (NI) (N=322)	Occasional injuries (OI) (N=328)	Recurrent injuries (RI) (N=47)	OI+RI (N=375)	* NI:OI+RI *p-value; ß- factor*
Gender					
Females	189 (59%)	138 (42%)	13 (28%)	151 (40%)	*0.006; 0.497*
Males	133 (41%)	190 (58%)	34 (72%)	224 (60%)	
Age (mean±SD)	41 years (11)	42 years (11)	44 years (10)	42 years (11)	*Lower leg only: 0.000; 0.947*
BMI (mean±SD)	23 kg/m^2 (2.7)	23.1 kg/m^2 (2.6)	23.8 kg/m^2 (2.3)	23,2 kg/m^2 (2.6)	*ns*
<25 kg/m^2	246 (76%)	263 (80%)	36 (77%)	299 (80%)	*ns*
≥25 kg/m^2	76 (24%)	65 (20%)	11(23%)	76 (20%)	
Running experience					
Less than 1 year	40 (12%)	9 (3%)	3 (6%)	12 (3%)	*ns*
1 to 3 years	109 (34%)	99 (30%)	5 (11%)	104 (28%)	*0.007; 0.348*
4 to 10 years	118 (37%)	157 (48%)	18 (38%)	175 (47%)	*ns*
More than 10 years	55 (17%)	63 (19%)	21 (45%)	84 (22%)	*ns*
Running distance per week					
Less than 10 km	29 (9%)	13 (4%)	4 (9%)	17 (5%)	*ns*
11 to 20 km	91 (28%)	69 (21%)	7 (15%)	76 (20%)	*ns*
21 to 30 km	112 (35%)	116 (35%)	9 (19%)	125 (33%)	*Foot only: 0.038; 0.453*
31 to 50 km	62 (19%)	90 (28%)	18 (38%)	108 (29%)	*Foot only: 0.036; 0.480*
More than 50 km	28 (9%)	40 (12%)	9 (19%)	49 (13%)	*ns*
Other sports activities					
Yes	282 (88%)	284 (87%)	40 (85%)	324 (86%)	*ns*
No	40 (12%)	44 (13%)	7 (15%)	51 (14%)	
Previous injury					
Yes	215 (67%)	156 (48%)	16 (34%)	172 (46%)	*0.000; 1.78*
No	107 (33%)	172 (52%)	31 (66%)	203 (54%)	
Barefoot Running					
Yes	31 (10%)	51 (16%)	7 (15%)	58 (15%)	*Lower leg only: 0.035; 0.523*
No	291 (90%)	277 (84%)	40 (85%)	317 (85%)	

OI+RI - cumulative number of all injuries together; NI:OI+RI – statistical comparison between non-injured to injured runners; ns – no significant differences; * - significant differences are given for the whole body, unless otherwise stated.

Table 3. Risk factors for running related injuries prevalence among participants of 18th Ljubljana Marathon (N=697).

Variable	No injuries (NI) (N=452)	Minor injuries (Mil) (N=131)	Major injuries (Mal) (N=114)	Mil+Mal (N=245)	NI:Mil+Mal; *p-value; ß-factor*
Gender					
Females	232 (51%)	59 (45%)	49 (43%)	108 (44%)	*ns*
Males	220 (49%)	72 (55%)	65 (57%)	137 (56%)	
Age (mean±SD)	42 years (11)	41 years (10)	43 years (11)	42 years (11)	*ns*
BMI (mean±SD)	22.9 kg/m^2 (2.5)	23.5 kg/m^2 (2.9)	23.2 kg/m^2 (2.7)	23.4 kg/m^2 (2.8)	*0.036; 1.057*
<25 kg/m^2	365 (81%)	93 (71%)	87 (76%)	180 (73%)	*0.028*
≥25 kg/m^2	87 (19%)	38 (19%)	27 (24%)	65 (27%)	
Running experience					
Less than 1 year	40 (9%)	7 (5%)	5 (4%)	12 (5%)	*ns*
1 to 3 years	141 (31%)	44 (34%)	28 (25%)	72 (30%)	
4 to 10 years	177 (39%)	62 (47%)	54 (47%)	116 (47%)	
More than 10 years	94 (21%)	18 (14%)	27 (24%)	45 (18%)	
Running distance per week					
less than 10 km	33 (7%)	8 (6%)	5 (4%)	13 (5%)	*ns*
11 to 20 km	112 (25%)	25 (19%)	30 (26%)	55 (22%)	
21 to 30 km	157 (35%)	47 (36%)	33 (29%)	80 (33%)	
31 to 50 km	102 (22%)	39 (30%)	29 (26%)	68 (28%)	
More than 50 km	48 (11%)	12 (9%)	17 (15%)	29 (12%)	
Running on official event					
First time	89 (20%)	18 (14%)	16 (14%)	34 (14%)	*ns*
One to five times	221 (49%)	80 (61%)	58 (51%)	138 (56%)	
Six to ten times	76 (17%)	18 (14%)	17 (15%)	35 (14%)	
More than ten times	66 (14%)	15 (11%)	23 (20%)	38 (16%)	
Preparation for marathon					
No special training	46 (10%)	6 (4%)	10 (9%)	16 (7%)	*ns*
Training alone	262 (58%)	81 (62%)	62 (54%)	143 (58%)	
Supervised formal training	94 (21%)	26 (20%)	27 (24%)	53 (22%)	
Self-organized informal group	44 (10%)	17 (13%)	14 (12%)	31 (13%)	
Official running club	6 (1%)	1 (1%)	1 (1%)	2 (1%)	
Other sports activities					
Yes	392 (87%)	114 (87%)	100 (88%)	214 (87%)	*ns*
No	60 (13%)	17 (13%)	14 (12%)	31 (13%)	
Barefoot Running					
Yes	57 (13%)	19 (15%)	13 (11%)	32 (13%)	*ns*
No	395 (87%)	112 (85%)	101 (89%)	213 (87%)	

Mil+Mal - cumulative number of all injuries together; NI:Mil+Mal – statistical comparison between non-injured to injured runners; ns – no significant differences

4 DISCUSSION

This retrospective self-reporting study on Slovenian long-distance runners revealed that they had over 50% of lifetime prevalence of RRI. One out of three runners sustained at least one minor RRI per season. Mostly injured body regions were knee and ankle with Achilles' tendon. Male gender, short running history, previous injury, and an increased BMI seem to increase risk of RRI in general. We also established higher risk for lower leg RRI with increased age and barefoot running, and increased risk for foot RRI in relation to weakly mileage.

Current reports show that 19%-79% sustain a RRI (7). The differences between studies originate from a non-uniform definition of RRI and from the enrolled study populations (9). The most common conclusions that one out of two runners sustained an RRI in life, and that one of three runners was injured per season, was confirmed also in our data. Individual factors identified by the literature suggest that the majority of RRI are of multifactorial origin. Most commonly, reported risk factor in prospective studies is previous injury in the past 12 months, followed by higher quadriceps angle of the knee (Q angle) and a running distance per week (over 40 miles/64 km) (4). Increased BMI, male gender, running experience, participation in races of greater distance, increase in days of training per week, increase in training distance per week, shoe age, and running throughout the whole year have also been reported as limited evidence risk factors for RRI (7, 10). Greater training distance (30-39 miles/50-64 km), age,

previous sports activity, and running on concrete surfaces were associated with greater RRI in female runners, whereas greater training frequency, running experience of 0-2 years, and weekly running distance of 20-29 miles/32-49 km were associated with more RRI in men (7, 10). Training distance per week has been shown as the only protective factor for RRI of the knee (7). The strongest general RRI risk factors established with our study concur with previous publications: male gender, running experience of 1-3 years, previous injury, and weekly running distance. The later was significant only from 20 to 50 km; we speculate too few participants with weakly distance over 50 km were enrolled. An increased lifetime RRI risk for fresh (1 to 3 years), but not novice runners in comparison to runners with longer history was revealed. This suggests a natural selection bias: fresh runners who get injured early in their running carrier probably discontinue with this sporting activity, and only people with more appropriate biomechanical running dispositions persist. When we specifically focused on lower leg RRI, then higher age and barefoot running stood out as significant risk factors. Lower leg question on the distributed questionnaire was targeting body regions below the knee, and above the ankle. Herein, we would find mostly diagnoses-related shin and calf muscle-tendons, and less likely activity-induced compartment syndrome or tibia/fibula stress fractures. The muscle-tendon lower leg problems are probably related to degeneration and stiffness with increasing person's age, as such tissue is being less resistant to overuse (11). Shin/calf pain may also be related to foot pronation, as it has been previously shown that feet become flatter in older adults (12). Barefoot running itself has been shown to reduce foot soft-tissue overuse RRI, but it has a tendency to increase stress fractures (13). Recent studies tried to evaluate the effect of barefoot running on running injuries without any strong evidence beside supporting a forefoot strike pattern that improves running efficiency (14). Running barefooted or in minimalistic shoes requires higher activity of extrinsic shin/calf muscles to avoid heel strike and to adjust for the running terrain (13). We would suggest that such overload results increase lower leg RRI. Nevertheless, we need to interpret barefoot running with caution due to self-reporting of RRI and limited number of runners involved in barefoot running. BMI was exposed as a risk factor for one season injury, but not as a life-time prevalence risk factor. Here, we probably come across another natural history bias: novice/fresh overweight runners involved in running either quit this activity early due to an injury, or lose weight and continue with an injury free running career.

By reviewing recent studies about body parts affected by RRI in long-distance runners, most them can be attributed to the knee (7.2%-50%), followed by the lower leg (9%-32.2%), the foot (5.7%-39.3%), and thigh (3.4%-38.1%). Less common sites were the ankles (3.9%-16.6%) and the hip (3.3%-11.5%) (7). The most common clinical diagnoses are represented by the iliotibial band syndrome, patellofemoral pain syndrome, stress fractures, medial tibial stress syndrome, Achilles tendon and calf injuries, meniscus injuries, and muscle injuries to the hamstrings and quadriceps (5, 15). Among marathon runners, men report more hamstring and calf problems, whereas women report more hip complains (16). Knees and ankles/Achilles in our study, encounter for more than 50% of all RRI, and there seems to be good correlation to the other authors. Knowing the overuse problems of these particular regions, preventive training programs need to be implemented. Cross-training was previously shown to reduce risk for RRI (17, 18), but we were not able to prove this in our study population. Despite the expectations, we were also not able to show that supervised training in a club or in a dedicated training group, influences RRI risks. It looks like a supervised training provides motivational effect of running, but improvements of training protocols in terms of RRI prevention are required. Three main target groups of RRI prevention can be exposed from this study: males, overweight runners (BMI≥25 kg/m2), and previously injured runners. Lessons learned from anterior cruciate injuries and hamstring muscle tears have clearly shown that both can be reduced with dedicated preventive exercise (19, 20). Both injuries are quite easy to detect after an abrupt injury, as sportsmen are unable to continue with sports without medical help. On the other hand, RRI overuse injuries are less stressful, there is a wide spectrum of problems, and lots of runners do not seek medical attention for minor injuries. Overweight novice runners require soft transition into running, and they should be stimulated to lose weight also by other means, not just running itself. Although the population with previous RRI seems an easily accessible target for secondary prevention, the studies on functional diagnostics were not able to delineate clear criteria for RRI (21-23). Unfortunately, secondary prevention in such cases can be relied only on personal expert opinions.

This study needs to be interpreted considering the following limitations: limited sample size, self-reporting of RRI in a form of questionnaire, voluntary participation, and retrospective data acquisition. But on the other hand, the response rate of nearly 6% and similar distribution of age, gender, and running distances (referring to publicly available data) allowed us to draw statistically important conclusions.

5 CONCLUSIONS

This self-reported retrospective study on Ljubljana Marathon participants revealed a 53% lifetime prevalence of running-related injuries, with the predominate

involvement of knee, ankle, and Achilles tendon. One out of three recreational runners experienced at least one minor running injury per season. Male gender, short duration of running experience, previous injury, and higher BMI are linked to an increased risk of RRI in general. Higher age and barefoot running do increase risk for specific lower leg RRI, and so does the weakly running distance of over 20 km regarding specific foot RRI.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The study protocol was approved by the Slovenian National Medical Ethics Committee (No. 174/08/14).

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PATIENT SAFETY CULTURE IN SLOVENIAN OUT-OF-HOURS PRIMARY CARE CLINICS

KULTURA VARNOSTI V SLOVENSKIH DEŽURNIH AMBULANTAH NA PRIMARNI RAVNI

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ABSTRACT

Introduction. Patient safety culture is a concept which describes how leader and staff interaction, attitudes, routines and practices protect patients from adverse events in healthcare. We aimed to investigate patient safety culture in Slovenian out-of-hours health care (OOHC) clinics, and determine the possible factors that might be associated with it.

Methods. This was a cross-sectional study, which took place in Slovenian OOHC, as part of the international study entitled Patient Safety Culture in European Out-of-Hours Services (SAFE-EUR-OOH). All the OOHC clinics in Slovenia (N=60) were invited to participate, and 37 agreed to do so; 438 employees from these clinics were invited to participate. We used the Slovenian version of the Safety Attitudes Questionnaire – an ambulatory version (SAQAV) to measure the climate of safety.

Results. Out of 438 invited participants, 250 answered the questionnaire (57.1% response rate). The mean overall score ± standard deviation of the SAQ was 56.6±16.0 points, of Perceptions of Management 53.6±19.6 points, of Job Satisfaction 48.5±18.3 points, of Safety Climate 59.1±22.1 points, of Teamwork Climate 72.7±16.6, and of Communication 51.5±23.4 points. Employees working in the Ravne na Koroškem region, employees with variable work shifts, and those with full-time jobs scored significantly higher on the SAQ-AV.

Conclusion. The safety culture in Slovenian OOHC clinics needs improvement. The variations in the safety culture factor scores in Slovenian OOHC clinics point to the need to eliminate variations and improve working conditions in Slovenian OOHC clinics.

Keywords:
safety culture, out-of-hours medical care, primary health care, Slovenia

IZVLEČEK

***Uvod**. Kultura varnosti je koncept, ki opisuje, kako odnosi med vodstvom in osebjem, njihova stališča, postopki in praksa varujejo bolnike pred škodljivimi dogodki zaradi napake v zdravstvu. Z raziskavo smo želeli raziskati kulturo varnosti v slovenskih dežurnih ambulantah na primarni ravni zdravstvenega varstva in določiti dejavnike, ki so povezani z njo.*

***Metode**. To je bila prečna opazovalna raziskava, ki je potekala v slovenskih dežurnih ambulantah na primarni zdravstveni ravni in je bila del mednarodne raziskave z naslovom Patient Safety Culture in European Out-of-Hours services (SAFE-EUR OOH). K sodelovanju smo povabili vse dežurne ambulante v Sloveniji (N=60), 37 jih je sodelovanje potrdilo. V teh ambulantah je bilo k sodelovanju povabljenih 438 zaposlenih. Uporabili smo slovensko različico lestvice Safety Attitudes Questionnaire - ambulatory version (SAQ - AV), s katero smo merili raven kulture varnosti.*

***Rezultati**. Od 438 povabljenih je vprašalnike izpolnilo 250 zaposlenih (57,1%). Povprečna vrednost lestvice SAQ - AV je bila 56,6±16,0 točke. Povprečna vrednost faktorja dojemanje vodstva je bila 53,6±19,6 točke, faktorja zadovoljstvo z delom 48,5±18,3 točke, faktorja ozračje varnosti 59,1±22,1, faktorja ozračje timskega dela 72,7±16,6 in faktorja sporazumevanje 51,5±23,4 točke. Zaposleni v regiji Ravne na Koroškem, zaposleni z izmenskim delom in zaposleni s polnim delovnim časom so imeli statistično višji seštevek točk na lestvici SAQ - AV.*

***Zaključek**. Kultura varnosti v slovenskih dežurnih ambulantah potrebuje izboljšave. Različni seštevki točk na lestvici SAQ - AV v različnih regijah Slovenije in v različnih dežurnih ambulantah kažejo na potrebo po zmanjšanju razlik in izboljšanju delovnih pogojev.*

Ključne besede:
kultura varnosti, dežurna služba, primarna zdravstvena raven, Slovenija

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1 INTRODUCTION

In the past two decades, quality in primary care has been extensively studied in Europe, including Slovenia (1-7). Several of these studies have dealt with patient safety issues, which is an important part of quality improvement (8-14). In Slovenia, patient safety features in primary health care have been investigated through the study on Quality and Costs of Primary Care in Europe (QUALICOPC), dealing with the organisation and accessibility of primary health care services (4, 15, 16).

Out-of-hours health care (OOHC) at the primary health care level is a crucial part of the availability and accessibility of the provision of healthcare (17, 18). Several studies have already been published on patient safety issues in OOHC and primary care emergency settings (8, 13, 18-21). Smits et al. reviewed patient records in OOHC clinics in the Netherlands, and determined that although patient safety incidents did occur in 2.4% of reviewed patients records in OOHC clinics, most did not harm the patients (8). A systematic review of the safety of telephone triage in OOHC clinics concluded that triage was safe in most cases. However, there was room for improvement in triage for patients who present with symptoms that indicate high risk (22). Patient safety culture in OOHC clinics as a concept, which describes how leader and staff interaction, attitudes, routines and practices protect patients from adverse events in healthcare, has been investigated in a few studies (13, 20, 21, 23). Bondevik et al. (13) found both demographic and professional differences in staff perception of patient safety in Norwegian OOHC clinics.

In Slovenia, primary OOHC clinics are located in primary health care centres. Medical care is provided mainly by family physicians with their teams, who also carry out emergency services. Slovenian OOHC clinics are open 24/7, enabling free access to patients on demand. In urgent cases, an emergency team with an ambulance is available. The team consists of a physician on call and two specialist nurses providing the emergency medical services (EMS). This is a major difference between Slovenian and most European OOHC clinics, as OOHC in the majority of the European countries is organised separately from the EMS (17).

To date, only one paper has dealt with patient safety culture in Slovenian OOHC clinics (24). We therefore decided to study this issue further to get some insight into this area. We aimed to investigate patient safety culture in Slovenian OOHC clinics, and determine the possible factors that might be associated with it.

2 METHODS

2.1 Type of Study and Settings

This was a cross-sectional study that took place in Slovenian OOHC clinics from 16 March to 1 May 2015. The study was part of an international study entitled Patient Safety Culture in European Out-of-Hours Services (SAFE-EUR-OOH), which was led by a coordinating research group from Norway. The study was a project by the European research network for out-of-hours primary health care (EurOOHnet) (25).

In Slovenia, there are 60 OOHC clinics and all were invited to participate; 37 of them agreed to do so. There are 10 health care regions in Slovenia, which correspond to geographical regions: Murska Sobota, Maribor, Ravne na Koroškem, Celje, Krško, Novo Mesto, Ljubljana, Kranj, Nova Gorica, and Koper. The participating OOHC clinics were grouped according to these regions: seven OOHC clinics from the Ljubljana region, five from the Kranj and Ravne na Koroškem regions, four from the Koper region, three from the Murska Sobota, Maribor, Celje, Krško, and Novo Mesto regions, and one from the Nova Gorica region.

2.2 Participants

In each OOHC clinic, the person in charge of data collection asked all the employees (physicians, nurse practitioners, nurse managers, trainees, practice nurses, radiology technicians, and office managers) to participate. Following this procedure, 438 people were invited to participate. The participation was voluntary and anonymous.

2.3 Data Collection

The key national researcher for Slovenia (ZKK) collected the e-mail addresses of all the invited employees of the 37 participating OOHC clinics in Slovenia. An e-questionnaire was sent by the coordinating research group in Norway to these employees on 16 March 2015. After two weeks, an automatic reminder was sent to those who had not responded. The e-questionnaires were sent using the computer programme, Qualtrics.

We used the Slovenian version of the SAQ-AV (24), which has been translated from English according to standard procedures (26). The SAQ-AV is a 62-item questionnaire where the respondents rate their agreement using a 5-point Likert scale: 1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, 5=agree strongly (27). "Not applicable" was included as a response category in all questions, and combined with missing values in the data analyses. The scores of negatively worded items were reversed, so that higher scores in the data set always indicated a more positive evaluation of the OOHC clinics' patient safety culture. Additionally, there were also some demographic questions (sex, age, function, work

experience, shifts, and type of employment). "Variable shifts" describes the different types of possible working hours: days, evenings, nights, and variable/rotating shifts. The Slovenian version of the SAQ-AV has five safety climate factors: Perceptions of Management, Job Satisfaction, Safety Climate, Teamwork Climate, and Communication (24). The total score of the SAQ-AV was calculated according to the Baker and Hershaw equation (28):

[(Σitems 1-62) * 100/(5 * 62)] * 1.25 – 25.

Similarly, the scores of the individual factors were calculated as:

[(Σitems) * 100/(5 * N of items)] * 1.25 – 25.

So, the minimum score was 0 and the maximum score was 100 for the overall SAQ-AV score, as well as for each of the factors.

2.4 Analysis

Statistical analysis was carried out using the SPSS 22.0 programme. We performed bivariate analysis using the independent t-test and one-way ANOVA, and multivariate analysis using linear regression. The variables that proved significant in the bivariate analyses were entered into the multivariate analysis. We set the limit of statistical significance at $p<0.05$.

3 RESULTS

3.1 Demographic Characteristics

Out of 438 invited participants, 250 answered the questionnaire (57.1% response rate). There were 110 (44.0%) women in the sample (Table 1).

3.2 Attitudes to Patient Safety Culture

The mean overall score ± standard deviation of the SAQ was 56.6±16.0 points; of Perceptions of Management 53.6±19.6 points; of Job Satisfaction 48.5±18.3 points; of Safety Climate 59.1±22.1 points; of Teamwork Climate 72.7±16.6; and of Communication 51.5±23.4 points.

The highest climate scores of patient safety culture were reported in the Nova Gorica region and the lowest in Koper. Perceptions of Management was scored highest in the Krško region, and Job Satisfaction, Safety Climate, Teamwork Climate, and Communication were scored highest in the Nova Gorica region. There were significant differences across regions in terms of the overall total SAQ-AV score, and of the climate factors Perceptions of Management, Job Satisfaction, and Communication (Table 2).

Table 1. Demographic characteristics of the Slovenian out-of-hours primary health care clinics' employees participating in the study (N=250).

Characteristic	N (%)
Sex	
Male	91 (36.4)
Female	110 (44.0)
Not given	49 (19.6)
Age (years)	
30 and lower	41 (16.4)
31-40	74 (29.6)
41-50	49 (19.6)
51-60	33 (13.2)
61 and higher	4 (1.6)
Not given	49 (19.6)
Usual shift	
Days	3 (1.2)
Evenings	2 (0.8)
Nights	4 (1.6)
Variable	192 (76.8)
Not given	49 (19.6)
Type of employment	
Full-time	191 (76.4)
Part-time	7 (2.8)
Contract	3 (1.2)
Not given	49 (19.6)
Work experience (years)	
5 or less	46 (18.4)
6-10	39 (15.6)
11-20	65 (26.0)
21-30	41 (16.4)
31-40	9 (3.6)
41 or more	1 (0.4)
Not given	40 (19.6)
Function	
Physicians	93 (37.2)
Nurse practitioners	43 (17.2)
Nurse managers	3 (1.2)
Trainees	15 (6.0)
Practice nurses	40 (16.0)
Radiology technicians	1 (0.4)
Office managers	7 (2.8)
Not given	48 (19.2)
Region of Slovenia	
Murska Sobota	7 (2.8)
Maribor	45 (18.0)
Ravne na Koroškem	34 (13.6)
Celje	15 (6.0)
Krško	15 (6.0)
Novo Mesto	21 (8.4)
Ljubljana	33 (13.2)
Kranj region	28 (11.2)
Nova Gorica region	2 (0.8)
Koper region	18 (7.2)
Not given	32 (12.8)

Table 2. The scores of SAQ-AV and its factors in the Slovenian out-of-hours primary health care clinics of different Slovenian regions.

	Murska Sobota	Maribor	Ravne na Koroskem	Celje	Krsko	Novo Mesto	Ljubljana	Kranj	Nova Gorica	Koper	P
	Mean (SD)										
Perceptions of Management	60.7 (27.5)	48.0 (22.1)	60.5 (13.5)	53.9 (16.4)	62.8 (11.0)	49.6 (20.7)	50.3 (18.9)	60.8 (12.5)	62.5 (11.8)	41.9 (25.6)	0.005
Job Satisfaction	50.6 (16.6)	45.0 (20.9)	57.7 (10.2)	41.7 (20.7)	51.7 (19.4)	41.5 (20.2)	51.4 (14.6)	50.5 (14.7)	66.7 (5.9)	43.5 (24.2)	0.018
Safety Climate	54.5 (24.1)	63.1 (22.7)	67.4 (14.6)	55.8 (16.1)	56.7 (31.2)	51.8 (22.7)	59.6 (21.3)	60.3 (19.6)	71.9 (4.4)	55.5 (24.7)	0.309
Teamwork Climate	76.2 (12.2)	65.4 (19.4)	77.8 (13.6)	67.2 (13.5)	75.6 (15.5)	73.0 (14.6)	74.2 (16.7)	77.7 (12.4)	79.2 (5.9)	69.9 (22.3)	0.055
Communication	47.6 (26.6)	48.2 (26.3)	59.3 (17.9)	41.1 (22.3)	52.8 (10.8)	49.2 (23.7)	60.1 (22.5)	51.0 (23.5)	87.5 (17.7)	44.9 (25.4)	0.033
Overall SAQ-AV score	57.9 (16.6)	53.6 (18.7)	64.5 (9.4)	51.9 (15.1)	57.5 (16.8)	52.7 (16.0)	58.5 (15.4)	60.1 (12.3)	73.5 (0.3)	51.2 (21.3)	0.035

Bivariate analyses for the overall total SAQ-AV score revealed that physicians (t=1.992, p<0.048), practice nurses (t=1.882, p=0.049), those working in variable shifts (t=4.842, p<0.001), those working full-time (t=5.581, p<0.001), and those working in the Ravne na Koroškem region (t=4.571, p<0.001) had significantly higher scores when compared to the other categories.

For the factor Perceptions of Management, bivariate analyses showed that those working in variable shifts (t=2.139, p=0.046), full-time (t=2.930, p=0.004), in the Ravne na Koroškem region (t=2.918, p=0.005), in the Krško region (t=2.827, p=0.012), and in the Kranj region (t=2.835, p=0.007) had significantly higher scores when compared to the other categories.

For the factor Job Satisfaction, bivariate analyses revealed that those working in variable shifts (t=4.022, p=0.001), full-time (t=4.550, p<0.001), and in the Ravne na Koroškem region (t=4.816, p<0.001) had significantly higher scores when compared to the other categories.

Bivariate analyses for the factor Safety Climate showed that practice nurses (t=3.821, p<0.001), and those working in variable shifts (t=4.506, p<0.001), full-time (t=5.514, p<0.001), and in the Ravne na Koroškem region (t=3.230, p=0.002) had significantly higher scores when compared to the other categories.

For the factor Teamwork Climate, bivariate analyses revealed that physicians (t=3.106, p=0.002), those working in variable shifts (t=2.489, p<0.001) or full-time (t=4.052, p<0.001), and participants working in the Maribor region (t=-2.735, p=0.009) had significantly lower scores when compared to the other categories.

Bivariate analyses for the factor Communication showed that physicians (t=2.075, p=0.039), those working in morning shifts (t=4.238, p<0.001), those not working in afternoon shifts (t=-6.064, p<0.001), those working in variable shifts (t=3.243, p=0.005), those working full-time (t=3.328, p=0.003), and those working in the Ravne na Koroškem region (t=2.122, p=0.035), in the Ljubljana region (t=2.146, p=0.033), and in the Nova Gorica region (t=2.208, p=0.026) had significantly higher scores when compared to the other categories. Participants working in afternoon shifts had significantly lower scores when compared to those working in morning, afternoon, or variable shifts.

Variables significantly associated with higher SAQ-AV scores in the multivariate analysis were employees working in the Ravne na Koroškem region, those with variable shifts, and those with full-time jobs. Higher scores in the factor Job Satisfaction were significantly associated with variable shifts, a full-time job, and working in the Ravne na Koroškem region. Employees working in variable shifts and having a full-time job scored significantly higher on both the Safety Climate and Teamwork Climate factors. On the contrary, those working in the Maribor region scored significantly lower on these factors. Employees working in variable shifts, having a full-time job, and working in the Ravne na Koroškem, Ljubljana and Nova Gorica regions scored significantly higher in the factor Communication (Table 3).

Table 3. Multivariate analysis for the scores of SAQ-AV and its five factors in the Slovenian out-of-hours primary health care clinics.

Dependent variable	Independent variables	B	95% CI	T	P
Overall SAQ-AV score[1]	Ravne na Koroskem region	7.46	2.24-12.67	2.82	0.005
	Physicians	2.98	1.14-7.11	1.43	0.155
	Practice nurses	1.54	3.90-6.99	0.56	0.577
	Variable shifts	13.70	6.27-21.14	3.63	<0.001
	Full-time job	14.30	7.14-21.57	3.93	<0.001
Perceptions of Management[2]	Afternoon shift	14.68	14.28-43.65	1.00	0.319
	Variable shifts	10.85	-0.53-22.23	1.88	0.062
	Full-time job	5.73	-4.78-16.24	1.07	0.284
	Maribor region	-4.60	-11.72-2.51	-1.27	0.204
	Ravne na Koroškem region	6.62	-1.12-14.36	1.68	0.093
	Krsko region	9.19	-2.15-20.55	1.59	0.112
	Kranj region	6.93	-1.47-15.34	1.63	0.105
	Koper region	-9.14	-18.72-0.43	-1.88	0.061
Job Satisfaction[3]	Variable shifts	21.84	13.48-30.20	5.15	<0.001
	Full-time job	19.17	10.98-27.36	4.61	<0.001
	Ravne na Koroskem region	9.71	4.11-15.32	3.42	0.001
Safety Climate[4]	Variable shifts	14.72	4.37-25.07	2.80	0.006
	Full-time job	19.93	9.67-30.19	3.83	<0.001
	Ravne na Koroskem region	5.48	-1.98-12.94	1.45	0.149
	Practice nurses	7.07	0.04-14.10	1.98	0.049
Teamwork Climate[5]	Variable shifts	8.26	0.02-16.50	1.98	0.049
	Full-time job	14.67	6.75-22.60	3.65	<0.001
	Practice nurses	-3.19	-9.08-2.70	-1,07	0.287
	Physicians	2.27	-2.50-7.06	0.94	0.349
	Maribor region	-8.25	-13.62-2.87	-3.03	0.003
Communication[6]	Variable shifts	19.15	3.65-34.65	2.44	0.016
	Full-time job	12.89	0.06-25.73	1.98	0.049
	Physicians	5.03	-1.02-11.09	1.64	0.103
	Morning shift	23.71	-9.95-57.38	1.39	0.166
	Afternoon shift	-0.82	-35.41-33.77	-0.05	0.963
	Ravne na Koroskem region	10.70	2.24-19.15	2.49	0.013
	Ljubljana Region	9.39	0.70-18.08	2.13	0.034
	Nova Gorica region	34.03	3.86-64.20	2.22	0.027

[1] $F=19.445$, df=5, $p<0.001$, adjusted $R^2=0.30$
[2] $F=3.981$, df=8, $p<0.001$, adjusted $R^2=0.10$
[3] $F=36.790$, df=3, $p<0.001$, adjusted $R^2=0.33$
[4] $F=18.266$, df=4, $p<0.001$, adjusted $R^2=0.24$
[5] $F=11.419$, df=5, $p<0.001$, adjusted $R^2=0.19$
[6] $F=6.286$, df=8, $p<0.001$, adjusted $R^2=0.16$

4 DISCUSSION

This was the first study investigating patient safety culture in Slovenian OOHC clinics (24). It showed that the Teamwork Climate scores were the highest and Job Satisfaction scores were the lowest among the employees. The fact that Teamwork Climate scores were the highest correlates with the results of the Slovenian study on ethical dilemmas in family medicine, where teamwork also seemed to be functioning well (29, 30). Teamwork as part of safety culture also scored high in hospital settings in Slovenia (10). Teamwork is very important in primary care, as health care providers with different professional backgrounds are engaged in the management of patients (31). This is also true for the OOHC clinics. In this setting, close cooperation between different professions is required (17). In fact, teamwork climate has been recognised as a key patient safety issue in OOHC clinics (24, 27, 32), and quality of performance seems to be associated with teamwork quality (33, 34).

Slovenian workers in OOHC clinics are, however, often not satisfied with their jobs, and this also seems to be reflected in their perceptions of patient safety culture. This finding was expected, as there is a big shortage of both physicians and nurses in Slovenia, and many are overburdened (35-37). In Slovenia, OOHC and emergency services are usually performed by the same team. Physicians often work in OOHC part-time, and in addition to their official working hours. In some regions, they work at two different job posts at the same time – in their own practice and in OOHC (17, 36). This is especially true for rural settings in Slovenia. Since the organisational domain is important in terms of safety culture (38), the varying organisational models in Slovenian OOHC clinics might be partly responsible for the observed differences in the SAQ-AV factor scores across the Slovenian regions.

Several factors contributed to the variation in climate scores across groups of employees in Slovenian OOHC clinics. Employees working as physicians or nurses, working in variable shifts and working full-time, had the highest scores. Working in variable shifts could contribute to a higher perception of patient safety, because the employees that work variable shifts may feel more competent to manage patients in different circumstances. The finding that working full-time possibly contributes to higher perception of patient safety is interesting. Studies have focused more on the impact of longer working hours and overtime working on patient safety (39), and we could not find any study on the associations between patient safety and part/full-time working hours. We anticipate that employees working part-time are not so confident in their performance (40), and thus perceive patient safety lower.

The scores of some factors varied across different Slovenian regions. This was especially true for the factors Perceptions of Management and Communication. Communication about safety issues in teams is very important and affects patient safety (41). It is probably connected to Perceptions of Management, as here also communication plays an important role.

It seems that the factors revealed to be important for a culture of safety in our study explained a large degree of the variation of the safety culture in Slovenian OOHC clinics, but according to the variances, the multivariate models explained are not the only ones.

Safety culture in OOHC has also been studied in Norway (13), and safety culture in emergency departments has been studied in the USA (21). In Norway and in the USA, the factor Job Satisfaction scored highest (13, 21), while in our study, it scored lowest. In our study, physicians scored significantly higher than nurses in Communication and Teamwork Climate, and in Norway (13), nurses scored higher in Safety Climate and Job Satisfaction. In the study from the USA (21), there were no differences between full-time and part-time workers regarding safety climate scores, which is not in line with the results of our study. It seems that safety climate in OOHC differs across countries, and further studies are needed to gain a deeper insight into these differences and their causes.

This study has some limitations. It aimed to include all OOHC clinics in Slovenia; however, only two-thirds of them were willing to participate. Similarly, only 250 respondents out of 438 invited employees filled in the questionnaire. Even though the proportion of participating clinics and the response rate of employees were moderately high, one still has to be careful about generalising the findings to the OOHC clinics of the entire country. On the other hand, the results of this study correlated with similar Slovenian studies, which gives us confidence in their reliability and validity.

5 CONCLUSION

Safety culture in Slovenian OOHC clinics needs improvement. The variations in safety culture factor scores in Slovenian OOHC clinics point to the need to unify working conditions in all Slovenian OOHC clinics. When planning safety culture improvements, the factors that were shown to be important in this study should be considered. We suggest reducing workload, more full-time employment, and educating communication and management skills. Further studies are needed to detect other possible factors important in safety culture in OOHC clinics, and to reveal the possible causes of the current situation.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The study was approved by the National Ethics Committee of the Republic of Slovenia (No. 25/11/14).

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IMPLEMENTING QUALITY INDICATORS FOR DIABETES AND HYPERTENSION IN FAMILY MEDICINE IN SLOVENIA

UVAJANJE KAZALNIKOV KAKOVOSTI ZA SLADKORNO BOLEZEN IN ARTERIJSKO HIPERTENZIJO V DRUŽINSKI MEDICINI V SLOVENIJI

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ABSTRACT

Introduction. A new form of family practices was introduced in 2011 through a pilot project introducing nurse practitioners as members of team and determining a set of quality indicators. The aim of this article was to assess the quality of diabetes and hypertension management.

Methods. We included all family medicine practices that were participating in the project in December 2015 (N=584). The following data were extracted from automatic electronic reports on quality indicators: gender and specialisation of the family physician, status (public servant/self-contracted), duration of participation in the project, region of Slovenia, the number of inhabitants covered by a family medicine practice, the name of IT provider, and levels of selected quality indicators.

Results. Out of 584 family medicine practices that were included in this project at the end of 2015, 568 (97.3%) had complete data and could be included in this analysis. The highest values were observed for structure quality indicator (list of diabetics) and the lowest for process and outcome quality indicators. The values of the selected quality indicators were independently associated with the duration of participation in the project, some regions of Slovenia where practices were located, and some IT providers of the practices.

Conclusion. First, the analysis of data on quality indicators for diabetes and hypertension in this primary care project pointed out the problems which are currently preventing higher quality of chronic patient management at the primary health care level.

Keywords:
family practices, healthcare quality indicator, diabetes mellitus, hypertension, Slovenia

IZVLEČEK

***Uvod**. Pilotni projekt na področju družinske medicine v Sloveniji je leta 2011 uvedel novo metodo dela v družinski medicini, pri čemer je nov član tima postala diplomirana medicinska sestra, prav tako pa se je uvedel nadzor kakovosti s pomočjo kazalnikov kakovosti. Namen tega članka je bil oceniti kakovost vodenja bolnikov s sladkorno boleznijo in hipertenzijo.*

***Metode**. V analizo smo vključili vse ambulante družinske medicine, ki so sodelovale v projektu konec decembra 2015. Iz avtomatične baze poročil smo izluščili in analizirali naslednje podatke: spol in specializacijo zdravnika, status zdravnika (javni uslužbenec, koncesionar), trajanje sodelovanja v projektu, regijo, v kateri je ambulanta, število prebivalcev na območju, ki ga pokriva ambulanta, računalniško hišo, ki nudi program, in raven izbranih kazalnikov kakovosti.*

***Rezultati**. Od 584 ambulant družinske medicine jih je imelo 568 (97,3%) popolne podatke in so bile vključene v analizo. Najvišja vrednost kazalnikov kakovosti je bila opazovana pri kazalnikih kakovosti pogojev (register diabetikov), najnižja pa pri kazalnikih procesa in izida. Vrednosti izbranih kazalnikov kakovosti so bile neodvisno povezane s trajanjem sodelovanja v projektu, nekaterimi regijami Slovenije in nekaterimi računalniškimi hišami, ki nudijo elektronsko podporo.*

***Zaključek**. Prva analiza podatkov kazalnikov kakovosti za diabetes in arterijsko hipertenzijo je pokazala na probleme, ki trenutno onemogočajo doseganje višje kakovosti obravnave bolnikov na primarni ravni zdravstvenega varstva.*

Ključne besede:
družinska medicina, kazalniki kakovosti, sladkorna bolezen, arterijska hipertenzija, Slovenija

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1 INTRODUCTION

Assessing quality of care with quality indicators is paramount (1) and has already become a standard for working in family practice in several countries (2-5). Various quality indicators are being used (6) and in some countries performance-related-pay based on quality indicators has been introduced (7-9).

In Slovenia, quality assurance at the primary health care level is formally a priority, but the legislation that would ensure quality in this area is proceeding very slowly. External quality assessment and inspections commissioned by the Ministry of Health are rarely used. Supervision of quality in primary care is fragmented and poorly coordinated. Family physicians (FPs) are more involved in unofficial and ad hoc forms of quality improvement than in formalised procedures. There are formal instruments for assessing quality, such as attestation of physicians, voluntary certification and accreditation, and mandatory licensing of physicians or nurses, but quality of primary health care has not yet been systematically assessed by quality indicators (10), despite the fact that a set of quality indicators was developed for cardiovascular prevention (11, 12) and that there is ample scientific evidence in this field in the literature (1, 5-7, 13-17)

In 2011, an ongoing pilot project at the primary care level in Slovenia was launched with the support of the Ministry of Health. It introduced a new model of family medicine practice where the family physicians' working team (consisting of one FP and one nurse with a baccalaureate degree – a practice nurse) was extended by a nurse practitioner working four hours a day or 0.5 full-time equivalents. The nurse practitioner is responsible for preventive activities (screening for and counselling on cardiovascular risk factors, diabetes, depression, chronic obstructive pulmonary disease (COPD), hypertension, and smoking and management of smoking and risky alcohol consumption) and routine management of patients with stable chronic diseases (COPD, asthma, hypertension, diabetes, benign enlargement of prostate, depression, osteoporosis and coronary heart disease) (18, 19). Preventive activities can also be carried out by physicians in terms of a comprehensive approach to the patients, but in this model of family medicine practice they are mainly performed by the nurse practitioners.

As part of this project, a list of quality indicators was introduced in order to monitor the work of family medicine practices participating in the project. The list included 35 quality indicators, of which nine were structure quality indicators, 23 were process quality indicators, and three were outcome quality indicators (1, 20).

The electronic database for collecting quality indicators was established at the beginning of 2015. Before that, data entry was manual and carried out by each practice itself into the Excel spreadsheets. There are five IT providers for family practices in Slovenia with their own data extraction systems, and data had to be gathered in one electronic database, which presented some problems at the start.

Hypertension and diabetes were among eight chronic diseases which were monitored by quality indicators, and are at the same time among the most common chronic diseases encountered in family medicine.

The aim of this article was to assess the differences in the values of the selected quality indicators between new model family medicine practices with different characteristics. The objective of this article was to conduct a relationship analysis between values of two selected indicators and some important characteristics of practices.

2 METHODS

We included all family medicine practices that were participating in the project in December 2015 as the source of data. The data were gathered from automatic electronic reports on quality indicators provided monthly by each individual family medicine practice. The data are stored in a common electronic database which can be used by project managers. For the purpose of the analysis, the following data were extracted: gender and specialisation of the family physician, status (public servant/self-contracted), duration of participation in the project, region of Slovenia, number of inhabitants covered by the family physician, name of the information technology (IT) provider, and quality indicators. The units of observation were family medicine practices with their staff (a physician, a practice nurse and a nurse practitioner).

At the end of 2015, there were 35 different quality indicators that family medicine practices reported on (20). For the purpose of this study, we chose one quality indicator from each different type (structure, process and outcome quality indicator (1) (Table 1).

Table 1. Quality indicators for diabetes and hypertension.

Quality indicator	Calculation formula	Type of quality indicator	Quality standard	Mean value (SD)	Median
List of patients with diabetes	Number of diabetic patients/ (Number of registered patients * 0.061) * 100	Structure	0	84.2 (53.6)	84.0
Percentage of patients with diabetes with measured HbA1C once a year	Number of patients with diabetes with measured HbA1C at least once a year/number of registered diabetic patients[2] * 100	Process	80	25.6 (22.3)	21.2
Percentage of patients with hypertension with a systolic blood pressure 140/90 mmHg or lower	Number of patients with hypertension with blood pressure 140/90 mmHg or lower/number of registered[3] patients with hypertension * 100	Outcome	50	18.2 (16.3)	14.3

[1] Prevalence of diabetes in Slovenia which is 6% (21)

[2] The expression "registered" describes the number of patients with diabetes/hypertension on the patient list of each family medicine practice

Statistical analysis was carried out using IBM SPSS Statistics version 22.0 (Armonk, NY: IBM Corp.). We performed multivariate analysis with general linear models. We set $p<0.05$ as the limit for statistical significance.

We used the observed outcome variables and explanatory factors in the analyses. The observed outcome variables were: 1) the value of the quality indicator "List of patients with diabetes"; 2) the value of the quality indicator "Percentage of patients with diabetes with measured HbA1C once a year" (continuous variable); and 3) the value of the quality indicator "Percentage of patients with hypertension with a systolic blood pressure 140/90 mmHg or lower" (continuous variable). Higher levels of observed outcome variables indicated a higher quality of work.

The explanatory factors were: 1) gender (nominal variable: male/female); 2) specialisation of family physician (nominal variable: has specialisation in family/ general medicine/does not have specialisation in family/ general medicine; 3) status of family medicine practice (nominal variable: public servant/self-contracted); 4) duration of participation in the project (continuous variable); 5) region of Slovenia (nominal variable: Celje, Koper, Krsko, Kranj, Ljubljana, Maribor, Murska Sobota, Nova Gorica, Novo Mesto, Ravne na Koroskem); 6) area covered by the practice (nominal variable: urban/rural); and 7) name of IT provider (nominal variable: IT No. 1, IT No. 2, IT No. 3, IT No. 4, IT No. 5). The variable "Urban/ rural area" was determined according to the definition of rural areas in Slovenia provided by the Statistical Office of Slovenia, which defines rural areas as those with less than 5,000 inhabitants.

The dummy variables created for the multivariate analyses were gender (reference category: male gender), the region of Slovenia (reference category: Ravne na Koroskem), the IT provider (reference category: IT provider No. 5), specialisation (reference category: no specialisation), area (reference category: urban), and status (reference category: public servant) and were created by a simple coding.

3 RESULTS

3.1 Sample Description

Out of 584 family medicine practices that were included in this project at the end of 2015, 568 (97.3%) had complete data and could be included in this analysis (Table 2). The mean duration of participation in the project was 28.7±18.7 months, with a median of 33.0 months. The mean age of the family physicians was 51.4±9.0 years, median 53.0.

Table 2. Characteristics of family medicine practices included in the project.

Characteristic	Number (%)
Region	
Celje	71 (12.5)
Koper	34 (6.0)
Krsko	20 (3.5)
Kranj	63 (11.1)
Ljubljana	148 (26.1)
Maribor	84 (14.8)
Murska Sobota	37 (6.5)
Nova Gorica	44 (7.7)
Novo Mesto	37 (6.5)
Ravne na Koroskem	30 (5.3)
Gender of the physician	
Male	132 (23.2)
Female	436 (76.8)
Specialisation of the physician	
General medicine	313 (55.1)
Family medicine	195 (34.3)
Other specialities	1 (0.2)
No specialisation	59 (10.4)
Status	
Public servant	426 (75.0)
Self-contractor	142 (25.0)
IT provider	
No. 1	159 (28.0)
No. 2	6 (1.1)
No. 3	210 (37.0)
No. 4	90 (15.8)
No. 5	97 (17.1)
Area	
Urban	459 (80.8)
Rural	109 (19.2)

3.2 Quality Indicator 'List of Patients with Diabetes'

The mean value of this quality indicator was 84.2±53.6, with a median of 84.0 (Table 1).

The results of a multivariate analysis showed that the variables 'IT provider No. 1 and 4' and 'Duration of participation in the project' were significantly correlated with a higher value of this quality indicator, and 'Working in the Maribor region' was significantly correlated with a lower value of this quality indicator (Table 3).

For continuous variables regression coefficients indicate the change of the observed variable with each increasing unit of explanatory variable.

For categorical variables regression coefficients indicate the changes of the observed variable in comparison to a reference category.

3.4 Quality Indicator "Percentage of Patients with Diabetes with Measured HbA1C Once a Year"

The mean value of this quality indicator was 25.6±22.3, with a median of 21.2.

The results of a multivariate analysis showed that the variable 'Duration of participation in the project' was significantly correlated with a higher value of this quality indicator, and 'IT provider No. 3 and 4' were significantly correlated with a lower value of this quality indicator (Table 4).

Table 3. Characteristics of family medicine practices included in the project.

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Gender				
Female	0.17	4.66	-8.97, 9.30	0.972
Male	reference			
Status				
Self-contractor	6.47	5.22	-3.76, 16.70	0.215
Public servant	reference			
IT provider				
No. 1	19.03	8.13	3.10, 34.96	0.019
No. 2	12.18	19.57	-26.18, 50.55	0.534
No. 3	8.88	6.53	-3.92, 21.67	0.174
No. 4	21.85	7.79	6.57, 37.12	0.005
No. 5	reference			

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Area				
Rural	-2.61	5.17	-12.74, 7.52	0.614
Urban	reference			
Specialisation				
General Practice	-2.92	6.99	-16.62, 10.78	0.676
Family Medicine	-0.46	7.00	-14.17, 13.26	0.948
No specialisation	reference			
Region				
Celje	-8.32	11.03	-29.94, 13.31	0.451
Koper	-1.99	11.92	-25.36, 21.38	0.868
Krsko	11.18	14.45	-17.14, 39.49	0.439
Kranj	4.02	10.70	-16.95, 24.99	0.707
Ljubljana	-4.58	9.42	-23.05, 13.88	0.627
Maribor	-35.92	10.97	-57.42, -14.42	0.001
Murska Sobota	-17.34	11.32	-39.52, 4.85	0.126
Nova Gorica	-0.40	11.00	-21.95, 21.15	0.971
Novo Mesto	0.37	11.45	-22.07, 22.80	0.975
Ravne na Koroskem	Reference			
Age (years)	-0.17	0.22	-0.61, 0.26	0.435
Duration of participation in the project	1.47	0.11	1.24, 1.69	< 0.001

Table 4. Multivariate analysis for higher value of the quality indicator 'Measured HbA1C in patients with diabetes at least once a year'.

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Gender				
Female	1.60	2.11	-2.53, 5.74	0.447
Male	Reference			
Status				
Self-contractor	1.03	2.37	-3.61, 5.66	0.664
Public servant	reference			
IT provider				
No. 1	-6.27	3.68	-13.49, 0.95	0.089
No. 2	-12.00	8.87	-29.38, 5.38	0.176
No. 3	-6.05	2.96	-11.85, -0.25	0.041
No. 4	-14.58	3.53	-21.50, -7.66	< 0.001
No. 5	reference			
Area				
Rural	-0.73	2.34	-5.32, 3.86	0.757
Urban	reference			
Specialisation				
General Practice	5.13	3.17	-1,07, 11.34	0.105
Family Medicine	3.34	3.17	-2.87, 9.55	0.292
No specialisation				

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Region	-9.28	5.00	-19.07, 0.52	0.063
Celje	-6.55	5.40	-17.14, 4.04	0.225
Koper	-4.37	6.54	-17.19, 8.46	0.505
Krsko	-6.37	4.85	-15.87, 3.13	0.189
Kranj	0.85	4.27	-7.51, 9.22	0.842
Ljubljana	3.88	4.97	-5.86, 13.62	0.435
Maribor	7.20	5.13	-2.85, 17.25	0.160
Murska Sobota	-9.18	4.98	-18.94, 0.58	0.065
Nova Gorica	-0.40	5.18	-10.56, 9.76	0.939
Novo Mesto	reference			
Ravne na Koroskem				
Age (years)	-0.11	0.10	-0.31, 0.08	0.265
Duration of participation in the project	0.30	0.05	0.20, 0.40	< 0.001

For continuous variables regression coefficients indicate the change of the observed variable with each increasing unit of explanatory variable.

For categorical variables regression coefficients indicate the changes of the observed variable in comparison to a reference category.

3.3 Quality Indicator 'Percentage of Patients with Hypertension with a Systolic Blood Pressure 140/90 mmHg or Lower'

The mean value of this quality indicator was 18.2±14.3, with a median of 16.3 (Table 1).

The results of a multivariate analysis showed that the variables 'Duration of participation in the project,' 'Female gender,' 'Self-contractor,' 'Working in the Maribor region' and 'Having IT No. 2' were significantly correlated with a higher value of this quality indicator. Variables 'IT provider No. 3' and 'IT provider No. 4' were significantly correlated with lower values of this quality indicator (Table 5).

Table 5. Multivariate analysis for higher value of the quality indicator 'Percentage of patients with hypertension with a systolic blood pressure 140/90 mmHg or lower.'

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Gender				
Female	3.36	1.48	0.47, 6.25	0.023
Male	Reference			
Status				
Self-contractor	3.44	1.65	0.20, 6.68	0.037
Public servant	reference			
IT provider				
No. 1	-0.77	2.57	-5.82, 4.27	0.764
No. 2	17.59	6.20	5.45, 29.74	< 0.001
No. 3	-6.64	2.07	-10.69, -2.58	0.001
No. 4	-10.58	2.47	-15.42, -5.74	< 0.001
No. 5	reference			

Explanatory variables	Regression coefficient	Standard Error	Upper and lower 95% confidence Interval	p
Area				
Rural	-1.65	1.64	-4.86, 1.56	0.314
Urban	reference			
Specialisation				
General Practice	2.05	2.21	-2.29, 6.39	0.354
Family Medicine	-0.95	2.22	-5.29, 3.39	0.668
No specialisation	reference			
Region				
Celje	-2.48	3.49	-9.32, 4.37	0.478
Koper	1.78	3.78	-5.62, 9.18	0.637
Krsko	-1.15	4.57	-10.11, 7.82	0.802
Kranj	-3.76	3.39	-10.40, 2.88	0.267
Ljubljana	1.65	2.98	-4.19, 7.50	0.579
Maribor	10.77	3.47	3.96, 17.57	0.002
Murska Sobota	5.33	3.58	-1.69, 12.36	0.137
Nova Gorica	-1.65	3.48	-8,47, 5.18	0.636
Novo Mesto	-0.43	3.62	-7.54, 6.67	0.905
Ravne na Koroskem	reference			
Age (years)	-0.06	0.07	-0.20, 0.07	0.368
Duration of participation in the project	0.15	0.04	0.08, 0.23	< 0.001

For continuous variables regression coefficients indicate the change of the observed variable with each increasing unit of explanatory variable.

For categorical variables regression coefficients indicate the changes of the observed variable in comparison to a reference category.

4 DISCUSSION

This study showed that the structure quality indicator was achieved for diabetes (list of diabetic patients). However, it also showed that the values of the process and outcome indicators were low, which indicates that the quality of management of patients with diabetes and hypertension could be improved. The levels of the selected quality indicators were associated with several features, most commonly with the duration of participation in the project, the region of Slovenia where the practice was located, and the IT provider used by the practice.

4.1 The Assessment of Quality of the Management of Patients with Diabetes and Hypertension

High values of structure quality indicators are an important sign that the conditions for measuring quality have been established. On the other hand, lower levels of process quality indicators were found and could be attributed to several reasons. The lack of continuous quality control with feedback could be one of them; the project continued without continuous data analysis, feedback to practices on the quality of their work, or benchmarking (22), and no staff were employed to carry out these tasks.

It is also possible that adherence to the guidelines was low. A recent study from Slovenia showed that the introduction of this different model of chronic patient management in family medicine improved the process of quality of care, but the desired level of quality has not yet been achieved (23), which probably points to low adherence to the guidelines. Other studies have also shown that primary care physicians' adherence to hypertension and diabetes guidelines is low (24-27). For example, adherence to hypertension guidelines was found to be between 10 and 50% (24, 25). On the other hand, another study showed that HbA1C was measured in almost all the patients (26).

It is also possible that the selection and development of the quality indicators themselves was not optimal. The development of quality indicators must be based on a systematic evidence-based approach, and expert consensus and guidelines should be considered. The indicators should be acceptable, feasible, reliable, sensitive to change, and valid (16). The quality indicators in our project have not yet been evaluated according to these features, and therefore it could be possible that the low levels of quality indicators are associated with their suboptimal nature.

4.2 Associations between Quality Indicators and Characteristics of Providers

The most important variable that was shown to be associated with higher levels of quality indicators was the duration of participation in the project. This indicates that the practical introduction of quality indicators in the everyday work of practices might be associated with some problems that could influence the quality. These problems are yet to be recognised. The region of practices was also recognised as important. Some previous data from Slovenia indicate that there are differences between regions in terms of quality (10). Which factors contribute to that is unknown and a subject for further studies. In addition, IT providers proved important in our research. Ensuring quality of data during electronic data capture is always a problem, and several ways of reducing errors must be applied (28, 29). There are no reports about the quality of data gathering in this project, and it therefore seems that there are some problems which still need to be recognised and addressed.

The quality indicator 'List of patients with diabetes' indicates the prevalence of diabetes in registered patients of family medicine practices in Slovenia. It should be mentioned here that its value could also be affected by the actual prevalence of diabetes in the region of Slovenia (30), and does not only depend on the quality of work.

Other factors can also contribute to the quality management of chronic patients and were not included in this study. These might include systemic factors, reimbursement, service organisation and capacity, cultural factors, disease epidemiology, practice systems in terms of incentives, practice information capacity, access, the use of teams in quality policy, detection of quality and safety problems, staff and patient safety, inclusion of patients' perspectives, and the length of consultations (31-34). These factors should be considered when studying this topic further.

4.3 Limitations of the Study

We chose only a few quality indicators because we focused on the management of chronic diseases and not on their prevention. This was done to ensure the clarity and focus of the study. It could, however, be possible that by excluding some quality indicators we overlooked some other differences.

The other problem is the quality of the data, as the electronic database was only established in 2015; our analysis was carried out at the end of 2015, and we can, therefore, anticipate that some technical problems had not yet been resolved. Therefore, the reliability of the data might not be as good as if we had done the research later.

Our study did not include other factors that could influence the quality of management of chronic diseases, especially the characteristics of other team members, particularly nurse practitioners. Since nurse practitioners are very involved in the management of chronic patients, the inclusion of their characteristics could have helped us to build a more comprehensive view of this matter, and produced more reliable statistical models. Other limitations are the exclusion of patient data, and the cross-sectional nature of this study, which prevents us from detecting causality. This would further increase the comprehensibility of the results.

In our study, we did not analyse the characteristics of those family medicine practices that did not participate in the project. Therefore, we do not know if they differ significantly from those included in the study.

4.4 Theoretical and Practical Implications of the Study

The study showed that the quality assessment was a challenge, because the values of the quality indicators were set empirically while preparing the new model of family medicine practices in Slovenia. The quality indicators should be re-evaluated and changed if necessary according to the established methodology (16). It was also recognised that expert supervision at the location is necessary to assess the process of work of the family medicine team at different levels (e.g. following protocols, regularly measuring the parameters of chronic diseases, recording them in the electronic database, and their reporting and analysis), and to discuss the obstacles directly with care providers. Continuous quality control and benchmarking should be established in order to improve the quality of chronic patient management in Slovenian family medicine practices. The study also indicated the need for collaboration between different professionals (e. g. IT specialists and health care providers) to adopt the IT system to fully support patient management. The quality indicators should be a basis for financing the practices according to quality standards. It may also be important to inform each team about their quality results every month, and ask for their feedback.

4.5 Suggestions for Future Research in the Field

The regional differences in quality which emerged from our analysis should be further explored. Other possible factors that could contribute to quality should be studied. The quality indicators should be reviewed each year, which would allow a comparison of indicators between two points in time in the same practice, or between practices using the new approach and those using the classical approach, and to observe the trend of change according to the existing circumstances.

5 CONCLUSION

The first analysis of data on quality indicators for diabetes and hypertension in this primary care project pointed out the problems which are currently preventing higher quality of chronic patient management at the primary health care level. There are problems with the quality of data, especially with the IT support, which should be recognised and eliminated.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

Ethical approval was not sought as no patients were involved in the study. The values of quality indicators were extracted from the whole pool of data and other data were gathered from the project database. The data on providers were anonymous.

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THE ROLE OF HEALTH SERVICES IN ENCOURAGING DISCLOSURE OF VIOLENCE AGAINST WOMEN

VLOGA ZDRAVSTVENIH USTANOV PRI SPODBUJANJU RAZKRITJA NASILJA NAD ŽENSKAMI

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ABSTRACT

Introduction. The aim of the survey was to assess the differences in disclosure by the type of violence to better plan the role of health services in identifying and disclosing violence.

Methods. A validated, anonymous screening questionnaire (NorAQ) for the identification of female victims of violence was offered to all postpartum women at a single maternity unit over a three-month period in 2014. Response rate was 80% (1018 respondents). Chi square test was used for statistical analysis ($p<0.05$ significant).

Results. There are differences in disclosure by type of violence. Nearly half (41.5%) of violence by health care services was not reported, compared to 33.7% physical, 23.4% psychological, and 32.5% sexual that was reported. The percentage of violence in intimate partnership reported to health care staff is low (9.3% to 20.8%), but almost half of the violence experienced by heath care services (44%) is reported. Intimate partnership violence is more often reported to the physician than to the psychologist or social worker. Violence in health care service is reported also to nurses.

Conclusions. Disclosure enables various institutions to start with the procedures aimed at protecting victims against violence. Health workers should continuously encourage women to speak about violence rather than asking about it only once. It is also important that such inquiries are made on different levels of health care system and by different health care professions, since there are differences to whom women are willing to disclose violence.

Keywords:
disclosure, differences by type of violence, encouraging disclosure of violence in health care

IZVLEČEK

***Uvod**. Namen raziskave je ugotoviti razlike v razkritju nasilja glede na različne vrste nasilja, da bi lahko ustrezneje načrtovali vlogo zdravstvenih institucij v identificiranju in razkrivanju nasilja.*

***Metode**. Na Ginekološki kliniki v Ljubljani smo leta 2014 opravili raziskavo z naslovom Nasilje med nosečnostjo - NANOS. Prevod in priredbo vprašalnika The NorVold Abuse Questionnaire - NorAQ smo na poporodnem oddelku tri mesece v anonimizirani obliki ponujali v izpolnjevanje vsem ženskam po porodu. Vprašalnik je razdeljen v 9 poglavij, ima 101 vprašanje in obsega 11 strani. Odzivnost je bila 80-odstotna (1018 respondentk) Rezultati so bili obdelani s statističnim paketom SPSS (SPSS for Windows version 21, IBM Corp., Armonk, NY, ZDA). Razlike med skupinami so bile testirane, upoštevajoč 95-odstotni interval zaupanja in statistično pomembnost pri $p < 0,05$.*

***Rezultati**. Rezultati kažejo na razlike v razkritju med različnimi vrstami nasilja. Podatki so pokazali, da približno tretjina žensk nikoli ne razkrije nasilja, ki ga doživljajo, in manj kot polovica tistih, ki o tem spregovorijo, razkrije celotno dogajanje. Manj kot polovico nasilja (41,5%) zdravstvenih delavcev respondentke niso prijavile, kar je višji odstotek kot pri drugih vrstah nasilja, kjer niso prijavile 33,7% fizičnega, 23,4% psihičnega in 32,5% spolnega nasilja. Zdravstvenemu osebju razkrije psihično, fizično ali spolno nasilje v intimnih razmerjih od 9,3 do 20,8% anketirank in 44% jih razkrije nasilje zdravstvenega osebja. Najpogosteje nasilje v intimnih razmerjih razkrijejo zdravnikom, psihologom in socialnim delavcem, nasilje zdravstvenih delavcev pa razkrijejo zdravnikom in medicinskim sestram. Najmanj posledic doživljajo zaradi nasilja zdravstvenih delavcev (posledice trpi 16,2%) in največ, če doživijo spolno nasilje (posledice trpi 55,3%). Pri spolnem nasilju tudi največ žensk ne razkrije nasilja, vendar zelo trpijo zaradi posledic (30,3%). Pomoč poišče manj žensk, kot jih trpi posledice nasilje. Pri fizičnem nasilju jih pomoč poišče le 10,9%, pri psihičnem 20,4% in pri spolnem 25%.*

***Zaključek**. Razkritje je ključno dejanje, ki omogoča, da različne institucije lahko sprožijo postopke zaščite žrtve pred nasiljem. Zdravstveni delavci bi morali kontinuirano (in ne le enkrat) spodbujati ženske, da spregovorijo o nasilju. Pomembno je, da o tem sprašujejo in k razkritju spodbujajo različni zdravstveni delavci na različnih ravneh zdravstvenega sistema. Čeprav razkritje v zdravstvu ni pogosto, se ravno zdravstvo srečuje z vsemi ženskami, zato lahko pomembno vpliva na razkritje.*

Ključne besede:
razkritje, razlike glede na vrsto nasilja, spodbujanje razkritja v zdravstvu

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1 INTRODUCTION

Violence against women during pregnancy attracted much professional attention in the past decades and became an important research topic in medicine as well. The reason is primarily the growing awareness of the multiple effects of violence on the physical and mental health of women and children. The World Health Organisation (WHO) studies on intimate partner violence (IPV) indicate that, on the global level, the average incidence of violence during pregnancy is between 4% and 12%. These estimates vary significantly between countries ranging from 1% and 70%. Approximately one third of cases include kicks and punches in the abdomen (1). The consequences of violence during pregnancy can be long-lasting, and can cause a life-long trauma in children. Violence threatens person's physical and mental health and may lead to homicide or suicide. The WHO pointed out that violence may lead to addictive behaviour, which causes additional damage to the child who may suffer the consequences of drug abuse and alcohol consumption (1).

Studies of violence before and during pregnancy most often focus on the prevalence, incidence, consequences and dynamics of violence, with data gathered using both quantitative and qualitative methods. The findings of those studies show that violence during pregnancy has multiple effects on health of the mother and the child, for example, low weight at birth, premature birth, a low gain of weight during pregnancy, kidney infection, antepartum haemorrhage, caesarean section, miscarriage or neo-natal death (2-4). Mental health problems are also frequent, for example, depression, post-traumatic stress disorder, panic disorder, anxiety, as well as abuse of various substances (5, 6). Violence can also cause lack of attachment to the child and lower rates of breastfeeding (1). It can cause physical injuries to fetus, such as bruises, broken bones, and stab wounds, and death in extreme cases (7). Several meta-analyses of existing studies of violence during pregnancy have been conducted (8-10) as well as many national studies. The latter are important because they are conducted in specific socio-cultural environments and structural conditions, so they can offer new insights. In addition, they are an important source of various comparisons and trans-national analysis.

Violence during pregnancy has not been a conspicuous research topic in Slovenia so far. A question referring to it was included in the national survey 'Violence against women in Slovenia' (11). Data showed that 5.5% of women experienced violence during pregnancy. Matko (12) conducted a qualitative study on the sample comprising 13 women who at the time of research, lived in the maternity home or the shelter for women, and who experienced violence during pregnancy. Her results show that 5 (38%) children were born prematurely. This is a much higher proportion of preterm birth compared to approximately 6% of preterm deliveries in the general population in Slovenia (13). More than half of children had health or other problems, such as developmental disorders, hyperactivity, dyslexia, or they needed learning support. Her conclusion is that women experience various kinds of violence during pregnancy. For some of them, physical violence began only during pregnancy and was followed by a ban on breastfeeding or other forms of restricting contact with the new-born. The consequences for women were emotional distress and physical injuries (12).

Violence against women is an important public health problem also because of high expenses of treatment of injuries caused by it. Female victims receive hospital treatment and need medicines more often than women who have no such experience (14). In the opinion of the Institute of Public Health's researchers, violence in Slovenia has not been sufficiently recognized as an important issue in public health, although there is a growing awareness of the problem (15). An important step forward was the adoption of the Rules on procedures for dealing with domestic violence in the implementation of health activities, which sets the professional and ethical standards of work with the victims of violence. The document imposes on health care workers the obligation to report violence, to cooperate within multi-disciplinary teams at centres of social work, and to assess the threat to the victim. The document further specifies that health workers should acquire relevant knowledge and skills through additional training programmes (16).

In 2014, the University Medical Centre Ljubljana, Division of Obstetrics and Gynaecology, Department of Perinatology, conducted the survey 'Violence during pregnancy – NANOS' that sought to establish the incidence of physical, psychological and sexual violence, as well as violence within the health care system before and during pregnancy. In addition, potential influences on the psychological and physical health of mothers and children were also studied. The study is a response to the growing responsibility of health workers to act upon the notice of violence and an important step in understanding the country's specific effects of violence on pregnant women. We used the translated and adapted NorVold Abuse Questionnaire – NorAQ, developed by Swahnberg and Wijma (17), which included questions on violence against women in health-care system due to negative effects that it might have on women and their capability of disclosing violence to health care workers.

In this article, we focus on data about the disclosure of violence and on the role of health care workers in the process of disclosure. The main research question is what are the differences in disclosure concerning the type of

violence and what are the differences in disclosure of violence experienced in intimate partnership or within the health care system. Results are important for future development of health care practices that will encourage women to disclose the violence.

2 METHOD

We conducted an observational cross-sectional study among all women who delivered at our perinatal centre during a three-month period. Quantitative and investigative research method was applied. We used the translated and adapted NorVold Abuse Questionnaire – NorAQ, developed by Swahnberg and Wijma (17). The questionnaire is divided into 9 sections and comprises 101 questions. The main sections include general questions about pregnancy, childbirth and contacts with gynaecologists, health, psychological abuse, abuse perpetrated by health care system, physical abuse, sexual abuse, current partnership, concluding questions, and an addition comprising 9 questions about childbirth. The questionnaire comprised 11 pages of easily comprehensible questions.

The anonymous questionnaire was offered to all postpartum women at a single maternity unit over a three-month period in 2014. Of the total 1272 women, 1018 responded, which amounts to 80% response rate. The questionnaire was available in print and online. Only 7 women chose online version.

The results were processed using the SPSS software (SPSS for Windows version 21, IBM Corp., Armonk, NY, USA). Differences between groups were tested using parametric and non-parametric tests, with confidence interval of 95% and statistical significance at $p<0.05$.

2.1 The Main Characteristics of the Sample

The average age of respondents was 31 years (the youngest one was 18 and the oldest 47); 32.8% of respondents had university education, 31.5% had secondary school education, 1.8% had only elementary school, and 1.6% had a doctoral degree. 52.1% of respondents are cohabitating, 46.5% were married, and 1.2% were single or divorced. As to the ethnic structure, 87% declared themselves as Slovenes, 5% as Serbs, 4.9% as Bosnians, with most of the remaining respondents coming from ex-Yugoslav republics and Eastern European countries. The percentage of employed women in the group was high. Of those, 72.3% said they were employed, 5.4% said that they were on a maternity leave, and 5.9% said that they were on a longer sick leave. Other respondents were either students or unemployed. Most women (85%) support their families along with their partners; 11% of respondents said that their partner was the only breadwinner in the family, and 2.4% said that they earned livelihood alone. As many as 33% said that they had no job guaranteed after the end of the maternity leave. Mobbing at a workplace was experienced by 10.4% of respondents. Sixty percent of respondents lived in their own dwellings, 22.1% in a rented accommodation, and 17.8% with their relatives or friends. One person lived in a maternity home. Approximately one quarter (25.9%) of respondents came from the rural area. Pregnancy was unplanned or undesired for 0.3% of respondents, while 25.9% of them did not plan it, but assessed it as desired. The sex of the child was deemed irrelevant by 69.2% of respondents, while 12.4% wished for a boy, and 18.4% for a girl. In the opinion of 67.9% of respondents, gender was irrelevant for their partners; 17.5% of partners wanted a boy, and 14.6% wanted a girl. One fourth of respondents had a miscarriage before current pregnancy, and 15% terminated pregnancy. One fourth already had a gynaecological surgery. Approximately one tenth of respondents assessed their health during pregnancy as poor; 24% visited a physician more than ten times during pregnancy, 38.2% up to three times, and 15.5% were hospitalised. Psychiatric help was sought by 3.4% of respondents during pregnancy. Approximately 15% experienced anxiety, and 11% were depressed.

Data point to some trends that are mirroring the societal change. More women live in co-habitation, the extent of employed is high, a vast majority is sharing the financial support of the family, although 11% is economically depended on their partners. Their future employment status is insecure, which reflects the precariousness of current employment patterns. For the tenth of them the workplace is a source of violence as they are experiencing mobbing. The ethnic structure of the sample reflects the ethnic structure of the Slovene society. For most couples, the gender of a child does not matter, but there are some differences between those that preferred a daughter or a son. Women whished more to have a daughter and men whished more to have a son. The health of women is an issue to be further explored. 15% of women who experienced anxiety and 11% who were depressed are relatively high percentages. A quarter of women also visited physician more than 10 times during pregnancy. Partly their psychological and physical condition can be explained with the age, but more in-depth research is needed.

2.2 Data on Violence Experienced in Different Life Periods

We sought to establish the presence of four types of violence, i.e. psychological, physical and sexual violence, as well as violence perpetrated by health care system. Table 1 shows the incidence of individual types of violence, enabling us to establish the scope of the phenomenon. Some women experienced violence as children and as adults, and some experienced several types of

violence simultaneously. Violence during pregnancy was experienced by 9.2% of respondents, most frequently by health care system. While most of the IPV is gender-specific, meaning that most of the perpetrators are men, violence in health care is performed by both genders.
Comparing to the national prevalence study on violence against women (11), our survey shows a slightly higher extent of physical violence (23% in national survey), significantly less psychological violence (49.9% in national survey), and a slightly higher extent of sexual violence (6.5%), which is the consequence of different methodology and age limits. The national study was asking for violence experienced after 15 years of age. The comparison is also difficult to make because some women experience more than one kind of violence at the same time, which is pointed out in the European survey on violence against women (18).

3 RESULTS

In Table 2, we compare data on disclosure of any kind of violence. Approximately one third of respondents reported violence they experienced, but not all types of violence were reported at equal rate. Violence perpetrated by health care system was the least reported, in contrast to psychological violence, which was most frequently disclosed. Approximately half of respondents who reported every instance of violence most frequently reported violence experienced by health care system.

There are differences regarding which health worker they choose to disclose a specific type of violence. Table 3 shows that while violence perpetrated by health workers is most often disclosed to the physician or the nurse at the primary level, other types of violence are more often reported to a psychologist, physician on a secondary or tertiary level, or a social worker, but not to a nurse.

Table 1. Incidence of individual types of violence in various periods of life.

Period of life	Physical violence	Psychological violence	Sexual violence	Violence by health care system	Any type of violence
Before the age of 18	22.4	14.8	6.1	2.7	31.2
In adulthood	9.5	14.1	2.0	10.1	19.1
During pregnancy	1.0	3.2	0.0	5.8	9.2
Whenever	29.2	26.1	7.6	16.1	46.9

Table 2. Disclosure to anyone.

% of disclosure	Physical violence	Psychological violence	Sexual violence	Violence by health care system
No	33.7	23.4	32.5	41.5
Yes, partly	21.8	29.4	26.0	10.2
Yes, everything	44.4	47.2	41.6	48.3

Table 3. Reporting violence to health care staff.

% of disclosure	Physical violence (N=13)	Psychological violence (N=21)	Sexual violence (N=7)	Violence by health care system (N=29)
Physician	46.2	28.6	42.9	65.5
Nurse	/	4.8	/	27.6
Psychologist	38.5	57.1	42.9	3.4
Social worker	15.4	9.5	14.7	3.4

Table 4. Disclosing violence to a health worker.

% of disclosure	Physical violence	Psychological violence	Sexual violence	Violence by health care system
No	90.7	79.2	80.4	56.0
Yes, he already knew	2.3	2.8	3.9	8.3
Yes, when he asked about it	2.9	7.3	9.8	10.7
Yes, I told it of my own will	4.1	10.7	5.9	25.0

Table 5. Seeking help after experiencing violence.

% of seeking help	Physical violence (N=256)	Psychological violence (N=225)	Sexual violence (N=76)	Violence by health care system (N=148)
No, since it did not cause much suffering	70.7	55.6	44.7	83.8
No, although I suffered a lot	18.4	24.0	30.3	11.5
Yes, I sought help	10.9	20.4	25.0	4.7

Table 4 shows that women speak about violence if asked about it by a physician. They more often report psychological violence, unlike about physical violence, which is rarely reported.

The research shows differences in the extent of the severity of various types of violence (Table 5). Violence committed by health workers causes least consequences, and sexual violence caused severe consequences for more than half of women who experienced it. A significant proportion of women (32.5%) do not disclose sexual violence, but the suffering caused by it is severe. Some women who experienced violence did not ask for help: one tenth of those who experienced physical violence, one fifth of those who were psychologically abused, and one third of those who were sexually abused.

4 DISCUSSION

Disclosure is an essential step that enables various institutions to start with the procedures aimed at protecting victims against violence. However, many obstacles prevent victims from disclosing violence. Distrust, shame and fear affect women's attitude towards various public services, and few women are willing to speak about violence. Women who have experienced violence seek health care due to physical injuries, but often they do not disclose the associated abuse or violence. 'A health-care provider is likely to be the first professional contact for survivors of intimate partner violence or sexual assault. Statistics show that abused women use health-care services more than non-abused women do. […] Health professionals can provide assistance by facilitating disclosure; offering support and referral; providing the appropriate medical services and follow-up care; or gathering forensic evidence, particularly in cases of sexual violence' (19). Research findings show the tendency to downplay violence as a problem issue. It has been shown that most victims presenting for social and health care are not asked about violence and do not receive attention or intervention (30).

Our research data show that approximately one third of women never disclose violence they experienced, while less than half of those who do report violence are willing to tell everything. 9.3% (counted together all 'yes' answers in Table 4), and 20.8% of respondents disclosed psychological, physical, or sexual violence in intimate relationships to health workers, while 44% disclosed violence perpetrated by health workers. Data points to a difference between IPV and institutional violence. Different research shows that women often tolerate violence in intimate partnership, fail to recognise it, find it difficult to resist, and even more difficult to leave such a relationship, because they frequently believe that the perpetrator loves them and that he will change (20). They seek reasons for violence in the problems of their partners, they tend to minimise the problem, and attribute it to their own behaviour (provoking the partner, refusing sex). Other reasons of staying in violent relationship include fear of retribution, a lack of alternative means of economic support, concern for the children, emotional dependence, a lack of support from family and friends, and an abiding hope that the partner will change (14).

Reasons for disclosing the institutional violence differ from IPV. The primary common feature of each type of violence is a wish to gain power and control, regardless of whether it is committed in IPV or elsewhere. It is a means taken by the perpetrator to acquire power over other members of a society and subordinate them (21). It should be noted,

however, that abuse in healthcare is defined by patients' subjective experiences of encounters with the health care system, characterized by devoid of care, where patients suffer and feel they lose their value as human beings (22). Violence in health care is performed by men and women alike, and research shows that the most common forms of violence against women are neglect, verbal violence, including rough treatment, threats, scolding, shouting, and intentional humiliation, then physical violence, including denial of pain-relief when technically indicated, and sexual violence, which is similar to the forms of violence that occur in IPV (23). The main difference between IPV and institutional violence that leads to a higher percentage of reported violence perpetrated by medical staff in our survey is a lack of emotional attachment and, consequently, a lack of tolerance to such practices. The percentage of women in our survey that did not disclose violence committed by medical staff is the highest, which is a paradoxical situation that needs to be further examined, because it points to the specific relationship between a patient and a physician. Power relations and hierarchical structures are significant for medical institutions, not just between physicians and patients, but also between different medical professions. Patients often subordinate to physicians because of the awareness of hierarchal positions (24). Such patients internalize social hierarchy and subordinated positions, and develop fear of disclosure. Others do not have such fear; they understand mechanisms within power relations and are, accordingly, capable of resistance. They have trust in medical knowledge, expect professional attitude based on mutual respect, and respect for dignity even if the situation involves uneven power relations (23). They refuse to accept inappropriate institutional conduct regardless of their own position in the social hierarchy. They do not defy the social prestige associated with medical profession, but are convinced that prestige does not imply superiority over patients (24).

Our research pointed to the difference between the disclosure of the IPV and of the violence within the health system, which is important when planning measures to prevent violence within health institutions. While physical and sexual violence in intimate partnerships is disclosed primarily to psychologists, physicians or social workers, violence perpetrated by medical staff is mainly disclosed to physicians and nurses. One of the reasons is that violence committed by health workers (excluding severe sexual or physical violence) does not cause as much suffering as violence in intimate partnership, so it is not reported to psychologists and social workers. Another reason is that in the case of violence perpetrated by health workers, the complaint procedure is better defined, which makes it easier for them to speak out. It is also important to stress that in our survey, physicians perpetrated the largest part of violence within the health system, so the victims speak about it to other health workers. This information is important in planning the ways to encourage disclosure of violence. Nonetheless, in the case of violence in health institutions, it is important to establish as independent as possible complaint procedures, and to ensure that IPV is reported in a personal contact with a physician. A nurse cannot pose questions about violence as part of routine inquiries before the patient encounters the physician. Much time and more visits are needed so that women can speak out, and in order to bring them to voice their problems, health workers' attitude must be respectful, so that women are encouraged to disclose violence. They will not speak out unless they believe that it is safe to disclose violence.

5 CONCLUSION

Institutional violence undermines public good (25) that should provide every person with dignity and respect. Health care institutions (as much as educational, social, cultural and other) are responsible to treat people equally regardless of their personal circumstances, and to broaden their choices for dignified life. They should understand power relations that are incorporated in medical system as much as in the relationship between a patient and a physician. 'However, addressing the problem of violence by health workers is necessary to support the efforts of dedicated staff who are committed to improving clinical practice' (23). It is important to sensitize health care providers and encourage routine screening for abuse, as well as to draw up protocols for proper management of abuse (28, 29).

To maximize efficiency when identifying the victims of violence, health workers should persistently encourage women to speak about potential violence rather than asking about it only once. There are tools available to screen women for IPV during obstetric care (26) that can be adopted to Slovene situation. It is also important that such inquiries are made on different levels and not only in primary health institutions (27, 31). The WHO emphasises that it is the public health institutions that encounter almost all victims of violence, so their staff needs to be highly trained to recognize violence and effectively handle it. Accordingly, they should establish cooperation with other institutions trained to handle violence, which will enable them to avoid excessive burden that could reduce the likelihood of dealing suitably with the problem. It is important to sensitize health care providers and encourage routine screening for abuse, as well as to draw up protocols for proper management of abuse. Confronting deep-rooted beliefs and attitudes is also important. Research suggests that making procedural changes in patient care has the greatest effect on the behaviour of health care providers (14).

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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KEY FACTORS DETERMINING INDOOR AIR PM_{10} CONCENTRATIONS IN NATURALLY VENTILATED PRIMARY SCHOOLS IN BELGRADE, SERBIA

KLJUČNI DEJAVNIKI, KI VPLIVAJO NA KONCENTRACIJO DELCEV PM_{10} V NOTRANJEM ZRAKU NARAVNO PREZRAČEVANIH OSNOVNIH ŠOL V BEOGRADU V SRBIJI

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ABSTRACT

Introduction. Indoor air quality (IAQ) is rated as a serious public health issue. Knowing children are accounted as more vulnerable to environmental health hazards, data are needed on air quality in schools.

Methods. A project was conducted from 2007 until 2009 (SEARCH, School Environment and Respiratory Health of Children), aiming to verify links between IAQ and children's respiratory health. Study was conducted in ten primary schools on 735 children, in 44 classrooms. Children were randomly selected. Research tools and indicators used for children's exposure to school environment were indoor and outdoor pollutants, two standardized questionnaires for school and classroom characteristics. In both classroom air and ambient air in front of them we measured, during a 5-day exposure period for continuous 24h measuring: carbon monoxide, carbon dioxide, indoor air temperature, relative humidity, and PM_{10} during classes.

Results. PM_{10} concentrations were significantly most frequent in an interval of ≥80.1μg/m^3, that is, in the interval above 50μg/m^3. Mean PM_{10} value was 82.24±42.43 μg/m^3, ranging from 32.00μg/m^3 to of 197.00μg/m^3.

Conclusion. The increase of outdoor PM_{10} concentration significantly affects the increase of indoor PM_{10}. A statistically significant difference exists for average IAQ PM_{10} concentrations vs. indicators of indoor thermal comfort zone ($p<0.0001$); they are lower in the classrooms with indicators within the comfort zone. Moreover, dominant factors for the increase of PM_{10} are: high occupancy rate in the classroom (<2m^2 of space per child), high relative humidity (>75%), and indoor temperature beyond 23°C, as well as bad ventilation habits (keeping windows shut most of the time).

Keywords:
indoor air quality, classrooms, particulate matter, PM_{10}, primary schools, exposure, Serbia

IZVLEČEK

***Uvod**. Kakovost notranjega zraka (IAQ) predstavlja resen javnozdravstveni problem. Ker so otroci bolj ranljivi za okoljska zdravstvena tveganja, so potrebni podatki o kakovosti zraka v šolah.*

***Metode**. Med leti 2007 in 2009 se je izvajal projekt (SEARCH, School environment and respiratory health of children - Šolsko okolje in respiratorno zdravje otrok), katerega namen je bil dokazati povezave med IAQ in respiratornim zdravjem otrok. Raziskava se je izvajala med 735 otroki v 44 učilnicah desetih osnovnih šol. Otroci so bili izbrani naključno. Zunanji in notranji onesnaževalci ter dva standardizirana vprašalnika o značilnostih šol in učilnic so služili kot raziskovalna orodja in kazalniki izpostavljenosti otrok šolskemu okolju. V zraku pred učilnicami in v njih so v 5-dnevnem neprekinjenem obdobju merjenja merili: ogljikov monoksid, ogljikov dioksid, temperaturo notranjega zraka, relativno vlažnost in PM_{10}.*

***Rezultati**. Koncentracije PM_{10} so bile pomembneje najpogostejše v intervalu ≥80,1 μg/m^3, torej v intervalu nad 50 μg/m^3. Povprečna vrednost PM_{10} je bila 82,24±42,43 μg/m^3 in je segala od 32,00 μg/m^3 do 197,00 μg/m^3.*

***Zaključek**. Povečanje koncentracij PM_{10} v zunanjem zraku pomembno vpliva na povečanje PM_{10} v notranjem zraku. Pojavljajo se statistično pomembne razlike med koncentracijami PM_{10} IAQ glede na kazalnike območja notranjega toplotnega ugodja ($p<0,0001$); nižje so v učilnicah s kazalniki znotraj območja udobja. Poleg tega so glavni vzroki za večje vrednosti PM_{10} sledeči: velika zasedenost učilnice (<2 m^2 prostora na učenca), visoka relativna vlažnost (>75 %) in temperatura notranjega zraka nad 23 °C, poleg tega pa tudi slabe prezračevalne navade (zaprta okna večino časa).*

Ključne besede:
kakovost notranjega zraka, učilnice, trdni delci, PM_{10}, osnovne šole, izpostavljenost, Srbija

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1 INTRODUCTION

The quality of indoor air of homes, offices, or other public or private dwellings could be accounted as one of the essential determinants of a healthy life and wellbeing of each individual (1). School indoor air quality (IAQ) is expected to have a key role in the assessment of children's personal exposure to air pollution, concerning the fact that they spend at least a third of their time inside school buildings, approximately 7 hours a day (2-5). Children are particularly vulnerable to all types of pollutants, because their breathing and metabolic rates are high. In a school, they have much less floor space than adults working in a typical office. Their breathing zone tends to be closer to pollutant sources, such as a new carpet, and less likely to be well ventilated, as it is below the window level. The immune system of young children is yet immature, and exposure to pollutants can mean allergic reactions or ill health (6).

Poor indoor environment in schools may be attributed to three primary causes: inexistence or inadequate operation and maintenance of ventilation systems, infrequent and unthoroughly cleaned indoor surfaces, and a large number of students in relation to room area and volume, with constant re-suspension of particles from the surface (1). Furthermore, IAQ can be attributed to various phases of the building process, including poor site selection, choice of materials, roof design, poor construction quality, improper installation, or any number or combination of these factors (7). Therefore, it is of utmost importance to provide good IAQ in classrooms, to help minimize these effects (8, 9). Sources of IA (indoor air) pollution could be: furnishings, IT equipment, bio-effluents, and external pollutants, such as nitrogen-dioxide and carbon-monoxide (3, 10-12). In the indoor environment, in which people spend most of their time, both indoor and outdoor sources contribute to PM levels. Indoor PM is affected by ambient concentrations, air exchange rates, penetration factors, as well as deposition and re-suspension mechanisms. In this complex microenvironment, activities such as cleaning, walking, playing, and, particularly, smoking cause the formation of PM in indoor air (13,14).

The main objective of this paper was to study the difference of PM_{10} concentration values, sampled both inside classrooms of ten Belgrade primary schools and in ambient air in front of them, and relate it to different classroom and school characteristics, using SEARCH Project methodology. A specific objective was to study the difference of concentration of the PM_{10} measurements inside and outside the chosen classrooms. In addition, we aimed to correlate a specific quantitative indicator of the thermal comfort zone, as given by the ASHRAE Standards (4), that is, space occupancy (<2m^2 of indoor space per child, not suitable), to the measured values of indoor PM_{10}.

2 METHODOLOGY

2.1 Sampling Site Description

The cross-sectional SEARCH (School Environment and Respiratory Health in Children) study has involved 6 European countries (Albania, Bosnia and Herzegovina, Hungary, Serbia, Slovakia, and Italy). In Serbia, the research was undertaken in the capital city of Belgrade. The project has defined that a sample of 10 schools per country shall be enough to get a clear picture on the level of indoor exposure of children in primary schools. They were chosen (sampled) to be with heterogeneous characteristics. Primarily, schools were grouped by their location, i.e. the level of their exposure to potential sources of air pollution in their vicinity (be it traffic or industrial facility), as suburb schools, schools in broader urban area, and downtown ones, shown in Table 1 (15). As for the vicinity of busy traffic, it can be easily comprehended by consulting the GIS map of their address, together with traffic characterisation (Figure 1). The criterion for the choice of a classroom was its orientation, either towards the street or to the school yard.

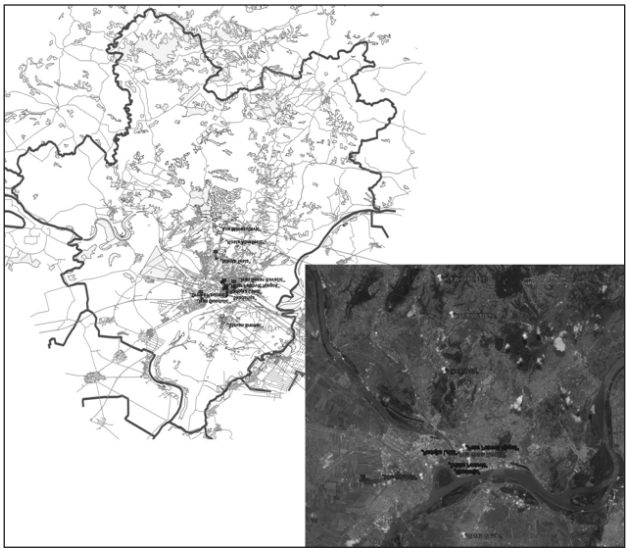

Figure 1. GIS map of 10 schools' geographic distribution on the Belgrade City map

Table 1. Characteristics of sampling sites.

School name	School code	Spatial characteristics of the surroundings	GIS coordinates
"Aca Milosavljevic"	1	Suburb Rušanj village, in the valley downhill the regional highway;	44°41'01,10" N 20°26'20,86" E
"Kosta Abrašević"	2	Suburb Resnik, residential area, trees in between the street and school	44°52'20,13" N 20°27'18,7" E
"Nikola Tesla"	3	Rakovica, suburban municipality, ex-industrial zone, ordinary urban traffic mode	44°42'33,95" N 20°27'06,52" E
"I. G. Kovačić"	4	Broad city centre, isolated from dense traffic, residential area;	44°49'18,19" N 20°24'15,75" E
"Skadarlija"	5	Downtown, high density traffic, backyard towards pedestrian zone, bus stop in front	44°44'30,27" N 20°25'44,89" E
"Stevan Sremac"	6	Borča III, urbanized suburb, with no heavy traffic	44°48'17,27" N 20°29'01,08" E
"Drinka Pavlović"	7	Downtown, close to two busy streets, 1 tunnel	44°48'16,20" N 20°27'43,91" E
"Petar Petrović Njegoš"	8	Downtown, high traffic density	44°48'21,72" N 20°27'21,81" E
"Radojka Lakić"	9	Squeezed between two streets with high density traffic (lots of heavy traffic), downtown, next to the Central Rail Station	44°49'06,12" N 20°27'49,41" E
"Ivan Gundulić"	10	New Belgrade, broader urban zone, frequent traffic	44°48'48,32" N 20°27'54,66" E

2.2 Monitoring Campaign

For both indoor and ambient air PM10 sampling, a portable HAZ-DUST EPAM-5000 particulate monitor (Ambient Portable Direct Reading Aerosol Monitor for Measuring Lung Damaging Airborne Particles) was used. It uses light scattering to measure particle concentration and provide real-time determinations and data recordings of airborne particle concentration in mg/m^3. By the model specification, its accuracy is ±10% to filter gravimetric SAE fine test dust; sensing range: .001-20.0 mg/m^3 or optional .01-200.0 mg/m^3 or 0.1-2000.0 mg/m^3; particle size range is .1-100 μm, and precision ±.003 mg/m^3 (3 $\mu g/m^3$) (16). For indoor air monitoring, it was positioned in classrooms, at 1.5 m height, away from the walls, to prevent influence of chipping. The monitor was positioned outside of the school building, in front of the indicated classroom, for ambient air PM_{10} sampling. Monitoring lasted for one whole working week, in both school shifts, while the children were present indoors, only. Monitoring lasted for 4 days during heating season in February 2008, simultaneously with the procedures undertaken in Albania, Bosnia and Herzegovina, and Slovakia. During each of the 4 measuring days, authors would fill in the checklist of the questionnaire for the classrooms, with details on the presence of pupils, and conditions concerning natural ventilation through the windows. Measuring instruments were looked after by the teachers (indoor) and authors who were mostly present in the school to check upon the equipment. The following measurements took place in the chosen classrooms: Combination of diffuse sampling during a 4-day exposure period for formaldehyde (HCHO), nitrogen dioxide (NO2), BTX, and continuous 24h measuring for carbon monoxide (CO), carbon dioxide (CO2) and PM_{10}, during school hours. Air temperature and relative humidity were measured as well. Parallel to these IAQ monitoring activities, outdoor air quality was followed for the same specific pollutants, close to school building (selected classroom). Besides air sampling procedures, the study protocol included two standardized questionnaires, namely: for school characteristics (filled in by the school administrator); for classroom characteristics (filled in by the teacher holding classes in it).

2.3 Statistical Methodology

Simple descriptive statistics, such as mean ± standard deviation, was used for continuous variables, IAQ and OAQ PM_{10}, the number and % of IAQ interval distributions, by schools and schools' position, while numbers (percentages) were used for categorical variables. The Kolmogorov-Smirnov test was used to check if IAQ and OAQ PM_{10}

had a normal distribution. Quantitative variables were compared using ANOVA F test, and categorical variables were compared using contingency tables and Chi-Square or Kruskal Wallis test. Chi-square test was used to compare IAQ PM_{10} between groups – schools or schools' position. For correlations between variables, we used Pearson Correlation for the linear relationship between two variables, by schools. A P-value less than 0.05 were considered statistically significant.

3 RESULTS

3.1 Geographic Positions of Schools

Table 2 shows comparative values of IAQ PM_{10} and OAQ PM_{10} by groups of schools. Both indoor and outdoor PM_{10} measured values are significantly higher in suburban schools than in those located in the broader urban zone: (for PM_{10} IAQ: K-W test=107.86, p<0.0001; PM_{10} OAQ: K-W test=39.43, p<0.0001). A similar level of significance appears when correlating values measured in suburban schools, with the values in schools located in the strictly urban zone: (K-W test=93.01; p<0.0001), and for PM_{10} OAQ, (K-W test=27.74; p<0.0001).

Indoor PM_{10} concentrations are significantly lower in schools located within a broad urban zone, when correlated to ones in a strictly urban zone, i.e.downtown (K-W test=12.943, p<0.0001). On the other hand, it does not count in the case of outdoor PM_{10} values (K-W test=2.228, p=0.135). PM_{10} IAQ measured values are significantly highest in suburban schools, (K-W test=133.454, p<0.0001), together with PM_{10} OAQ, (K-W test=69.86, p<0.0001).

Among schools, a statistically significant difference is proved for the distribution of IAQ PM_{10} concentration (p<0.0001). School 4 has significantly higher frequency of measured values IAQ PM_{10} in the range lower than 50 g/m^3. On the other hand, schools No. 1, 2, 3 and 8 had highest average values, and in all of them each of measured indoor concentrations was in the interval beyond 50 μg/m^3 (Table 3).

Table 2. IAQ and OAQ PM10 concentration related to school's geographic positions (μg/m^3).

Type of schools by location		No. of exposed children	Mean	SD	95% Cor Mean		Median/ Range	Min	Max
					Lower	Upper			
PM_{10} IAQ	Suburb schools	244	109.18	47.66	103.17	115.19	96/164	33	197
	Schools in broader urban area	220	66.08	37.36	61.12	71.05	53/126	32	158
	Downtown	271	71.09	26.90	67.88	74.31	70/79	32	111
	Total	735	82.24	42.43	79.17	85.31	70/165	32	197
PM_{10} QAQ	Suburb schools	244	153.90	130.39	137.46	170.34	116/515	34	549
	Schools in broader urban area	220	83.46	55.77	76.05	90.87	55/168	22	190
	Downtown	271	77.30	28.53	73.89	80.72	80/89	30	119
	Total	735	104.57	89.85	98.07	111.08	82/527	22	549

Table 3. Interval distribution IAQ PM10 Concentration >50 or ≤49.9 μg/m^3 by schools

PM_{10} ranges	School 1	School 2	School 3	School 4	School 5	School 6	School 7	School 8	School 9	School 10
≤49.9 μg/m^3	0.0	0.0	0.0	**67.2**	39.7	23.4	32.1	0.0	57.8	37.8
>50 μg/m^3	**100.0**	100.0	100.0	32.8	60.3	76.6	67%	**100.0**	42.2	62.2

The following Table 4 presents indoor PM_{10} mean concentrations (μg/m^3), standard deviation, median and range. The maximum concentration values of PM_{10} (162.12±41.93 μg/m^3) was registered in school No. 2, while a significantly lower concentration value of PM_{10} (44.72±12.48 μg/m^3) was at school 4 ($p<0.001$), and its value is below 50 μg/m^3.

Ambient air mean concentration of PM_{10} (μg/m^3), together with standard deviation, median and range by groups and schools, is given in Table 5. The maximum concentration values of PM_{10} in ambient air (320.82±137.79 μg/m^3) were in front of a suburban school No.2, while significantly lower concentration values of PM_{10} OAQ (38.33±9.65 μg/m^3) were outside school 6, located in the broad urban area, slightly hidden away from frequent traffic flow ($p<0.01$), with a value below 50 μg/m^3. The highest average values of both IAQ PM_{10} and OAQ PM_{10} concentration are accounted to school 2 (suburb schools).

Table 4. IAQ PM_{10} (μg/m^3) concentration by schools.

School Groups	School	PM_{10} (μg/m^3)	IAQ	Ci 95%		Median	Range
		Mean	SD	Lower	Upper		
Suburban	„A.Milosavljevic“	109.16	18.440	105.48	112.84	105.00	46.00
	„K. Abrasevic“	**162.12**	41.926	151.97	172.27	183.00	106.00
	„S. Sremac“	62.47	23.592	57.11	67.82	52.00	63.00
Broad urban area	„Nikola Tesla“	99.70	45.620	89.35	110.06	72.00	107.00
	„I. G. Kovacic“	**44.72**	12.479	41.53	47.92	38.00	30.00
	„I. Gundulic“	50.40	6.224	49.03	51.77	53.00	16.00
Downtown	„Skadarlija“	58.24	18.276	54.12	62.36	70.00	46.00
	„D. Pavlovic“	65.68	26.899	58.26	73.09	51.00	63.00
	„P.P. Njegos“	103.87	8.523	101.92	105.82	110.00	18.00
	„R. Lakic“	52.31	11.222	49.51	55.12	44.00	26.00

Table 5. Outdoor PM^{10} (μg/m^3) concentration by schools.

School Groups	School	PM_{10} (μg/m^3)	OAQ	Ci 95%		Median	Range
		Mean	SD	Lower	Upper		
Suburban	„A.Milosavljevic“	105.84	26.945	100.46	111.21	106.00	78.00
	„K. Abrasevic“	**320.82**	137.797	287.47	354.18	309.00	380.00
	„S. Sremac“	68.27	36.277	60.04	76.51	41.00	85.00
Broad urban area	„Nikola Tesla“	134.00	55.399	121.43	146.57	141.00	135.00
	„I. G. Kovacic“	80.33	35.626	71.20	89.45	75.00	84.00
	„Ivan Gundulic“	**38.33**	9.648	36.21	40.45	42.00	26.00
Downtown	„Skadarlija“	83.64	30.003	76.88	90.41	96.00	87.00
	„D. Pavlovic“	69.85	31.935	61.05	78.65	52.00	83.00
	„P.P. Njegos“	98.00	13.862	94.83	101.17	101.00	46.00
	„R. Lakic“	51.17	3.444	50.31	52.03	51.00	9.00

Descriptive statistical analysis of the data for particulate matter mass concentrations (PM_{10}) measured outdoors and in the classrooms, by schools is given in Table 6. None of the 10 schools satisfies the World Health Organization (WHO) standard for PM_{10} annual average of 20 μg/m^3 (17, 18). However, they meet the National Ambient Air Quality Standards (12) and WHO standards for PM_{10} 24-hour average, which have been set at 150 μg/m^3 and 50 μg/m^3, respectively (19).

Table 7 presents the distribution of the occupancy rate (according to ASHRAE) for each school, in m^2 per present child in the indicated classroom. Values are given as the percentage of children exposed to overcrowdedness (<2m^2/per child), or to convenient spatial conditions (>2m^2/per child). Indicators of crowdedness are the number of children in the classroom (less/more than 20), and space available in the classroom, per one child, of less/more than 2m^2 (4). Statistically significance is proven for the distribution of occupancy rate (m^2/per child), for each school, $\chi 2=340.70$, $p<0.0001$.

4 DISCUSSION

As an outcome of our study, when differentiating between OAQ PM10 and IAQ PM10 concentration values in relation to some classroom and school characteristics, we singled out the following moments: the highest average values of IAQ PM10 and OAQ PM10 concentration were measured in the school No. 2 (suburb school), while only in one school measured values IAQ PM10 were below 50 μg/m^3, that is in the school No. 4. The school No. 10, located in New Belgrade, in a broader urban zone with frequent traffic, had PM10 outdoor mean value below 50 μg/m^3, which could be explained with the terrain's topography. New Belgrade is, in geographical means, a flat terrain, with broad boulevards and widely spread buildings, belonging to the geographical entity of the Pannonian plain, enabling the build-up of high ambient air concentrations of traffic-related pollutants. This particular school is located in a residential block, built in the 1960s. School building is encircled by greenery and residential buildings, acting as

Table 6. Correlations between IAQ and OAQ by school (signif.)

School	PM_{10} outdoor median (μg/m^3)	PM_{10} indoor median (μg/m^3)	R	P	N
„A.Milosavljevic“	106.00	105.00	0.799	0.000	99
„K.Abrasevic”	309.00	183.00	0.756	0.000	68
„N.Tesla”	141.00	72.00	0.457	0.000	77
„I.G.Kovacic”	75.00	38.00	0.956	0.000	61
„Skadarlija”	96.00	70.00	0.598	0.000	78
„S.Sremac”	41.00	52.00	0.744	0.000	77
„D.Pavlovic”	52.00	51.00	0.937	0.000	53
„P.P.Njegos”	101.00	110.00	0.725	0.000	76
„R.Lakic”	51.00	44.00	0.160	0.207	65
„I.Gundulic”	42.00	53.00	0.453	0.000	82

Table 7. Child occupancy rate per school distribution (m^2/per child) vs. PM_{10} values (μg/m^3), by schools.

School No.	School name	<2 m^2/child	>2 m^2/child	IAQ PM_{10} mean
1	„A.Milosavljevic“	77.8	22.2	109.16
2	„K.Abrasevic”	/	100	162.12
3	„N.Tesla”	/	100	99.70
4	„I.G.Kovacic”	16.4	83.6	44.72
5	„Skadarlija”	38.6	61.4	58.24
6	„S.Sremac”	/	100	62.47
7	„D.Pavlovic”	/	100	65.68
8	„P.P.Njegos”	47.4	52.6	103.87
9	„R.Lakic”	/	100	52.31
10	„I.Gundulic”	/	100	50.40

a physical barrier to three streets with very busy traffic, of which one is the E-75 highway. It was, moreover, reported by the City of Belgrade Institute of Public Health, that in 2008, a series of days in a row were characterized with SE (south-east) wind ('Košava'), with episodes of wind speed reaching 12m/s, which caused a decrease of concentration of all ambient air pollutants measured by this institution (20).

A statistically significant correlation exists between PM10 indoor and outdoor concentration for each school ($p<0.0001$), except for the school No. 9, 'Radojka Lakic' ($p=0.207$), although it is located in a strictly urban zone, close to the juncture of two streets with very busy traffic. The increase of outdoor PM10 concentration is significantly correlated to the increase of indoor PM10 values (except for the school No. 9).

Considering this school, located close to the heavy traffic and Central rail station, with no statistical significance between indoor and outdoor measurement, we can conclude that, in this case, indoor concentration could be influenced by activities and movements of occupants, allowing re-suspension of previously deposited particles or their delayed deposition or settling. Fromme et al. found an average indoor particulate matter concentration higher than corresponding outdoor level in a German primary school (21). Similar was confirmed in a Belgian survey (22). Oeder et al. detected indoor PM10 concentration even 5-fold higher than outdoor ones in six schools in Munich (23). In addition, the presence of children, together with their movements, could affect indoor PM levels through the interception of personal clouds (primarily comprising of course particles), recorded by sampling devices (1).

In the school No. 1, which is both in the suburb and has all its measured values of IAQ PM10 beyond 50 μg/m^3, with an average PM10 IAQ of 109.16±18.44 μg/m^3, a significantly higher number of children is exposed to classroom indoor environment in a space with less than 2 m^2 per child. Concerning the fact that there is no busy traffic close to the school, high occupancy rate, together with bad ventilation habits and cleaning practice could be the reason for such results. This may be due to large number of students in relation to the room area and volume, whose movements cause re-suspension of settled particles (24).

In the school No. 8, 47.4% of its pupils have less than 2 m^2 per child, while all measured IAQ PM10 were above 50 μg/m^3, in which case the high occupancy rate could be accounted for one of the reasons for it. Some authors have determined that re-suspension is a significant factor affecting indoor particle concentration with suspension rates increasing with the particle size (25).

The school No. 4 is worth mentioning, with only its 16.4% pupils residing in the space with <2 m^2 per child, located in a broad urban zone of the city. IAQ PM10 values were below 50 μg/m^3, with the average PM10 IAQ concentration being the lowest compared to other schools, 44.72±12.48 μg/m^3.

On the contrary, the school No. 3 has 100% PM10 IAQ measurements in space with >2 m^2 per child, located in a broader urban zone, with all measured values of IAQ PM10 beyond 50 μg/m^3. The average indoor PM10 concentration in it is 99.70±45.62 μg/m^3. This school is cleaned mostly with the broom, and combined with the use of chemicals. This cleaning practice, being predominant as a cleaning pattern in this school, obviously facilitates the process of particle re-suspension (24).

As one of the defined elements of the thermal comfort zone, occupancy rate was chosen to be one of the key indicators in this study, together with CO2 indoor concentration, relative humidity, and classroom air temperature. Statistically significant smaller chances exist for formaldehyde indoor concentrations to be below 1.01 mg/m^3 in classrooms with more than 2 m^2 of space per child. For indoor CO2 concentration to increase above 1000 ppm, the number of children in the classroom above 20 (N>20) is a statistically significant predictor. Namely, chances for CO2 concentrations to be higher than 1000 ppm are 3.6-fold bigger in classrooms hosting more than 20 children. For indoor (classroom) air temperature within a comfort zone, a statistically significant predictor is classroom crowdedness, i.e. space in square meters per child. In fact, chances for indoor temperature to be within the comfort zone are less likely to occur in classrooms with less than 2 m^2 of space per child (4). For indoor values of relative air humidity, a statistically significant predictor is classroom crowdedness, i.e. space in square meters per child. In other words,, chances for this parameter to be within the comfort zone are close to 18-fold higher in classrooms hosting less than 20 children. Chances for PM10 to be below 50μg/m^3 are smaller, with high statistical significance, in classrooms hosting more than 20 children, having a blackboard, with chalk to write on.

The average indoor PM10 concentrations are lower in the classrooms where indicators of thermal comfort zone are satisfactory. In the school No. 4, the average indoor PM10 concentration is lower in classrooms with achieved standards for indoor comfort zone indicators, with high statistical significance Z - test=6.540, $p<0.0001$, while in the schools No. 5 ($Z=0.105$, $p=0.916$), No. 8 ($Z=1.614$, $p=0.107$) and No. 10 ($Z=0.948$, $p=0.343$) it is lower, but with no such high significance. Significantly highest mean values of IAQ PM10 concentration was measured in the schools 1, 2, 3 and 8, where comfort zone was not achieved ($p<0.001$).

Values of classroom indoor PM10 concentrations, from measurements in similar studies in different countries, during the heating season, are close to the values reported in this study in Serbia: in three schools in Portugal, PM10 average concentrations ranged from 30 to 146 μg/m^3; in a German study implemented in 64 urban and rural schools, it was 105 μg/m^3 (16.3-313.2 μg/m^3), while in HESE study, IAQ was monitored in 21 schools, both urban and rural, with the average PM10 concentration 112 μg/m^3 (91-133 μg/m^3) (1, 10, 26).

In most of the SEARCH1 countries, ambient PM10 concentrations were significantly increased in school zones close to frequent traffic streets, compared to those located further from such sources of air pollution. On the other hand, this difference in the traffic frequency of streets surrounding schools, has not significantly influence IAQ PM10 concentrations measured in classrooms, pointing that key sources of this pollutant are mainly in classrooms themselves (15). In the case of Belgrade study, as a part of the mentioned research, 36.2% of pupils study in classrooms with I/O PM10 ratio beyond 1.0, where the key source of PM10 is within the room; 3.7% is in classrooms with the ratio equal to 1.0., while 60.1% attend classes in rooms with the ratio below 1.0, where the source of a particulate matter is in ambient air, mostly from traffic in the vicinity of school buildings.

Although the city is located close to two coal burning power plants (Obrenovac, Kolubara), traffic is seen as the most powerful source of air pollution. Air back trajectories analysis showed that the prevalence of stagnant or week flow regimes (calm conditions) favours the suspension and accumulation of particles produced locally, resulting at the elevation of suspended particles levels (20, 27).

If we compare the location of Belgrade, on the banks of Sava River, with another region on its banks in Zasavje Region in Slovenia, with PM10 ambient air concentration, we spot some differences. Firstly, it is an issue of topography, as Zasavje is surrounded by steep hilly terrain, while Belgrade spreads in parts of the Pannonian Plain. Secondly, sources of air pollution are different in these two cases. In Zasavje, it is the case of industrial PM10 emissions (36.3μg/m^3), while in SEARCH1 Belgrade study, traffic was attributed as the key source for high PM10 levels (104.7 μg/m^3) (15, 28).

5 CONCLUSIONS

The majority of surveyed children is exposed to high indoor PM10 concentrations (560/735; 76.2%). Maximum PM10 values were measured in suburban schools, away from busy traffic. The increase of outdoor PM10 concentration significantly affects the increase of indoor PM10 values. Concerning an insufficient achievement of standards for indicators of indoor thermal comfort zone, dominant factors for the increase of PM10 are: high occupancy rate in the classrooms (<2 m^2 of space per child), high relative humidity (>75%) and indoor temperature beyond 23ºC; bad ventilation habits (keeping windows shut most of the time).

As the authors suggest, measures for the improvement of conditions in classrooms are as follows: schools should be built in places not directly affected by heavy traffic or industry, or any other polluting establishments in the neighbourhood; crowdedness should be avoided in the classrooms; appropriate ventilation regime of the classrooms should be introduced in order to provide good indoor air quality during the whole period of teaching hours, especially in classrooms directed towards crowded streets with presumably high ambient air pollution; in schools being ventilated only through natural means, but located close to traffic-induced air pollution, installing air-conditioning units should be taken into consideration. Cleaning practices should be standardized.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

In the case of the Republic of Serbia, if there is no direct contact with body fluids, tissues, personal contact concerning individual dignity, through questionnaires, researchers are not required to apply for the permission to research at the Ethical Committee. This study was not implemented on individual subjects, but was concerned only with the positioning of the standardized air quality measuring equipment in the classrooms and outside the same classrooms, for which, the REC project office had direct communication with school directors. Especially, when the moment of the equipment turning on/off was performed while classrooms were empty, with no physical contact with the pupils whatsoever.

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CLINICAL PROFILE AND MANAGEMENT OF PATIENTS WITH INCIDENT AND RECURRENT ACUTE MYOCARDIAL INFARCTION IN ALBANIA – A CALL FOR MORE FOCUS ON PREVENTION STRATEGIES

KLINIČNI PROFIL IN ZDRAVLJENJE PACIENTOV S PRVIM IN PONOVNIM POJAVOM AKUTNEGA MIOKARDNEGA INFARKTA V ALBANIJI – POZIV ZA VEČJO POZORNOST NA PODROČJU PREVENTIVNIH STRATEGIJ

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ABSTRACT

Background. The clinical profile of acute myocardial infarction (AMI) patients reflects the burden of risk factors in the general population. Differences between incident (first) and recurrent (repeated) events and their impact on treatment are poorly described. We studied potential differences in the clinical profile and in-hospital treatment between patients hospitalised with an incident and recurrent AMI.

Methods. A total of 324 patients admitted in the Coronary Care Unit of 'Mother Teresa' hospital, Tirana, Albania (2013-2014), were included in the study. Information on AMI type, complications and risk factors was obtained from patient's medical file.
Logistic regression analyses were used to explore differences between the incident and recurrent AMIs regarding clinical profile and in-hospital treatment.

Results. Of all patients, 50 (15.4%) had a prior AMI. Compared to incident cases, recurrent cases were older (P=0.01), more often women (P=0.01), less educated (P=0.01), and smoked less (P=0.03). Recurrent cases experienced more often heart failure (HF) (OR=2.48; 95% CI: 1.31–4.70), impaired left ventricular ejection fraction (OR=1.97; 95% CI: 1.05–3.71), and multivessel disease (OR=6.32; 95% CI: 1.43–28.03) than incident cases. In-hospital use of beta-blockers was less frequent among recurrent compared to incident cases (OR=0.45; 95% CI: 0.24–0.85), while no statistically significant differences between groups were observed regarding angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, statin, aspirin or invasive procedures.

Conclusion. A more severe clinical expression of the disease and underutilisation of treatment among recurrent AMIs are likely to explain their poorer prognosis compared to incident AMIs.

Keywords: acute myocardial infarction, epidemiology, in-hospital treatment, prevention, Albania

IZVLEČEK

***Ozadje**. Klinični profil pacientov z akutnim miokardnim infarktom (AMI) odraža breme dejavnikov tveganja v splošni populaciji. Razlike med prvim in ponovnimi pojavi in njihovim vplivom na zdravljenje so slabo opisani. Raziskali smo morebitne razlike v kliničnem profilu in bolnišničnim zdravljenjem pri pacientih s prvim pojavom AMI in tistih s ponovnim pojavom.*

***Metode**. V raziskavo je bilo skupno vključenih 324 pacientov, ki so bili v letih 2013-2014 sprejeti na Enoto za koronarno nego bolnišnice Matere Terezije v Tirani v Albaniji. Iz kartotek pacientov so pridobili podatke o vrsti AMI, zapletih in dejavnikih tveganja.*
Za ugotavljanje razlik med prvimi in ponovnimi AMI so bile uporabljene analize logistične regresije z upoštevanjem kliničnega profila in bolnišničnega zdravljenja.

***Rezultati**. Med vsemi pacienti jih je 50 (15,4%) že enkrat doživelo AMI. V primerjavi s pacienti s prvim pojavom so bili tisti s ponovnimi pojavi starejši (P=0,01), pogosteje so bile to ženske (P=0,01), imeli so nižjo izobrazbo (P=0,01) in so manj kadili (P=0,03). Pacienti s ponovnimi pojavi so v primerjavi s pacienti s prvim pojavom pogosteje izkusili odpoved srca (OR=2,48; 95% CI: 1,31-4,70), oslabljeno izmetno frakcijo levega prekata (OR=1,97; 95% CI: 1,05-3,71) in multivaskularno bolezen (OR=6,32; 95% CI: 1,43-28,03). Uporaba beta-blokatorjev v bolnišnični obravnavi je bila manj pogosta pri pacientih s ponovnim pojavom v primerjavi s pacienti s prvim pojavom AMI (OR=0,45; 95% CI: 0,24-0,85), medtem ko ni bilo opaziti statistično pomembnih razlik v zvezi z uporabo zaviralcev angiotenzinske konvertaze/blokatorjev receptorjev angiotenzina, statinov, aspirina ali invazivnih postopkov.*

***Zaključek**. Resnejša klinična slika bolezni in manjša poraba zdravil med pacienti s ponovnim pojavom AMI tako lahko razložita njihovo slabšo prognozo v primerjavi s pacienti s prvim pojavom AMI.*

***Ključne besede:** akutni miokardni infarkt, epidemiologija, bolnišnično zdravljenje, preventiva, Albanija*

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1 BACKGROUND

Acute myocardial infarction (AMI) is the most serious clinical expression of coronary heart disease (CHD). The substantial reduction in mortality following an incident (first) AMI (1-4), combined with aging of the population has led to a growing number of AMI survivors who are at risk of experiencing a recurrent (repeated) event. Although recurrent events account for the minority of all AMI-related hospitalisations (5, 6), their prognosis is poor (7-9), contributing thus substantially to the overall cardiovascular mortality.

Incident events reflect the burden of coronary risk factors in the population at large (10), whereas recurrences are further influenced by the quality of coronary care during the acute phase of the incident event and secondary prevention (11).

In Albania, CHD death rates are among the highest in the Southeast Europe (12). The burden of CHD (both mortality and hospitalisations) has increased in the last decades (13), rendering it the main cause of premature mortality in Albania (14). Simultaneously, the prevalence of classical coronary risk factors in the population is high. A health survey conducted in 2001 in Tirana, reported that among 1120 participants aged 25 years or older, the prevalence of obesity, diabetes mellitus (DM), hypertension and smoking (current) was 29% (15), (9.7%) (16), 31.8% (17) and 28% (18), respectively. Later reports confirmed the high burden of these risk factors; the prevalence of hypertension and obesity (in 2008) and smoking (in 2011) were 36.5%, 21.6% and 26% (19), respectively. Despite these unfavourable developments, the difficult transition from a totalitarian communist regime toward a free, marked-oriented economy in Albania was characterised by the lack of sufficient resources allocated to health care (20). As a consequence, preventive strategies have not been considered a priority. No structured national or regional primary prevention strategies have been applied at the population at large, despite their proven role in reducing CHD burden (21). Further, no structured rehabilitation programmes are available to coronary patients, and secondary prevention is confined to medical advice provided by specialists upon hospital discharge and, occasionally, during check-ups at the family doctor's office. The consequences of such lack of preventive strategies on the clinical profile of AMI patients and their management are not studied in Albania, and are poorly described elsewhere.

Thus, the objective of the current study was to explore the clinical profile and in-hospital treatment of patients hospitalized with an AMI, with a special focus on the differences between patients with and without history of prior AMI.

2. SUBJECTS AND METHODS

2.1 Study Population

This study included 324 consecutive patients hospitalized during 2013-2014, with an AMI in the Coronary Care Unit (CCU) of the University Hospital Centre 'Mother Teresa',' the only public hospital providing specialized coronary care in Tirana, the capital of Albania.

2.2 Data Collection

Information on patients' age, gender, educational attainment, height and weight, systolic and diastolic blood pressure, AMI type [ST-elevation myocardial infarction (STEMI) versus non-ST-elevation myocardial infarction (NSTEMI)], location, major complications [including heart failure (HF), ventricular fibrillation (VF) and 2nd or 3rd degree atrioventricular block (AVB)], and in-hospital treatment was obtained from patients' medical charts.

To derive the prevalence of each major risk factor, we combined self-reported information on risk factors and medication use prior to hospitalisation with blood pressure, fasting glucose, and total cholesterol values measured during admission (22). A history of prior AMI was defined as a previous hospitalisation with AMI as the main discharge diagnosis.

2.3 Statistical Analyses

Continuous variables were presented as means and standard deviations (SD), and categorical variables were presented as percentages. Independent sample t-test was used to compare mean values of the continuous variables. Categorical variables were compared using the chi-square test or Fisher's exact test in cases of small sample sizes.

Logistic regression models were used to explore differences between incident and recurrent cases regarding AMI complications and in-hospital treatment. They were adjusted for covariates known to influence the outcome, and showed association with the exposure in our data. To account for the role of comorbidities in a potentially influencing use of beta-blockers [chronic obstructive pulmonary disease (COPD), systolic blood pressure (SBP)<85 mm Hg or AVB], angiotensin-converting enzyme inhibitors (ACEI)/angiotensin receptor blockers (ARB) (SBP<85 mm Hg) and aspirin (peptic ulcer), we repeated the analyses after excluding patients with any of these conditions. The results of these analyses (referred to in the text as 'additional analyses') are presented as supplemental material online.

We tested and did not find a statistically significant interaction between gender and history of prior AMI. All models were adjusted for age and gender, and results expressed as odds ratios (OR) and 95% confidence intervals (CI) for prevalent versus incident (the reference

category) AMIs. Two-sided tests with the 0.05 significance level were used. Analyses were performed using STATA software, version 13.

3. RESULTS

3.1 Characteristics of the Study Population

Characteristics of the study population are summarized in Table 1. The mean (SD) age of the cohort was 64.4 (11.4) years and the majority (73.8%) were men. Overall, 44.1% of patients had attained only primary education and 55.9% secondary or tertiary education.

The prevalence of current smoking, hypertension, diabetes mellitus (DM), and hypercholesterolemia was 59.9%, 83.3%, 50.6% and 55.3%, respectively. At least one major risk factor was observed in 98.8%, and all four major risk factors in 13.9% of the study cohort.

3.2 The Clinical Profile of Patients

STEMI accounted for 83.9% of the study population (Table 2). AMI was complicated with HF in 33.6% of the patients. The proportion of impaired LVEF, 2nd or 3rd degree AVB or VF in the study population were 31.2%, 4.0% and 4.9%, respectively. Compared to incident cases, recurrent cases had multivessel CHD (P=0.03), HF (P<0.01), or impaired LVEF (P=0.01) (Table 2).

Table 1. Characteristics of the study population.

Patient characteristics	All patients (n=324)	Incident cases (n=274)	Recurrent cases (n=50)	P value
Age (years), mean (SD)	64.4 (11.4)	63.7 (11.5)	68.4 (10.1)	0.01
Gender (male), n (%)	239 (73.8)	210 (76.6)	29 (58.0)	0.01
Education, n (%)				
Primary	143 (44.1)	113 (41.2)	30 (60.0)	0.01
Secondary or higher	181 (55.9)	161 (58.8)	20 (40.0)	
Coronary risk factors, n (%)				
Smoking	194 (59.9)	171 (62.4)	23 (46.0)	0.03
Hypertension	270 (83.3)	229 (83.6)	41 (82.0)	0.78
Diabetes	164 (50.6)	135 (49.3)	29 (58.0)	0.26
Hypercholesterolemia	179 (55.3)	149 (54.4)	30 (60.0)	0.46
At least one risk factor	320 (98.8)	270 (98.5)	50 (100.0)	0.39
All four risk factors	45 (13.9)	39 (14.2)	6 (12.0)	0.63
Comorbidities, n (%)				
Atrial fibrillation	39 (12.1)	26 (9.4)	13 (27.7)	<0.01
Peripheral artery disease	23 (7.1)	20 (7.2)	3 (6.4)	0.84
Cerebrovascular disease	25 (7.4)	19 (6.9)	6 (12.8)	0.16
COPD	17 (5.3)	14 (5.1)	3 (6.4)	0.71
eGFR<60 mL/min/1.73m^2	77 (23.8)	59 (21.5)	18 (36.0)	0.03
Peptic ulcer	23 (7.1)	19 (6.9)	4 (8.0)	0.79
Pulse (beats/min), mean (SD)	78 (16.8)	77 (16.5)	80 (18.5)	0.37
Hemoglobin* (g/dl), mean (SD)	12.8 (1.9)	12.9 (1.8)	11.9 (1.9)	<0.01

COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate.

* 4% of patients had missing values

Incident cases were younger (P=0.01), more often men (P=0.01), and had attained a higher education (P=0.01) than recurrent cases. No statistically significant differences between groups were observed regarding hypertension, DM, and hypercholesterolemia. Smoking was more frequent among the incident cases (P=0.03).

Table 2. Clinical profile and in-hospital treatment of patients with an acute myocardial infarction.

	All patients (n=324)	Incident cases (n=274)	Recurrent cases (n=50)	P value
		Clinical profile		
STEMI, n (%)	271 (83.9)	230 (84.3)	41 (82.0)	0.69
Multivessel CAD, n (%)	164 (75.9)	136 (73.1)	28 (93.3)	0.03
Heart failure, n (%)	109 (33.6)	81 (29.6)	28 (56.0)	<0.01
LVEF<0.45, n (%)	101 (31.2)	77 (28.1)	24 (48.0)	0.01
AVB (2nd/3rd degree), n (%)	13 (4.0)	10 (3.7)	3 (6.0)	0.44
VF, n (%)	16 (4.9)	11 (4.0)	5 (10.0)	0.07
		In-hospital treatment		
Beta-blockers	192 (59.3)	172 (62.8)	20 (40.0)	0.01
ACEI/ARBs	206 (63.6)	179 (65.3)	27 (54.0)	0.12
Statins	314 (96.9)	268 (97.8)	46 (92.0)	0.05
Aspirin	308 (95.1)	261 (95.3)	47 (94.0)	0.71
All four drug classes	144 (44.4)	128 (46.7)	16 (32.0)	0.05
Invasive procedures				
Coronary angiography	222 (68.5)	192 (70.1)	30 (60.0)	0.16
Revascularization*	139 (64.4)	122 (65.6)	17 (56.7)	0.34

STEMI: ST-segment elevation myocardial infarction; CAD: coronary artery disease; LVEF: left ventricular ejection fraction; AVB: atrioventricular block; VF: ventricular fibrillation; ACEI: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker.
* Percutaneous coronary intervention or coronary artery bypass grafting among patients undergoing coronary angiography.

The results of age and gender-adjusted analyses revealed an increase in the odds of HF (OR=2.48; 95% CI: 1.31–4.70), impaired LVEF (OR=1.97; 95% CI: 1.05–3.71), or multivessel CAD (OR=6.32; 95% CI: 1.43–28.03) among recurrent cases compared to incident ones. No statistically significant differences were observed between groups regarding AMI type and other complications (Figure 1).

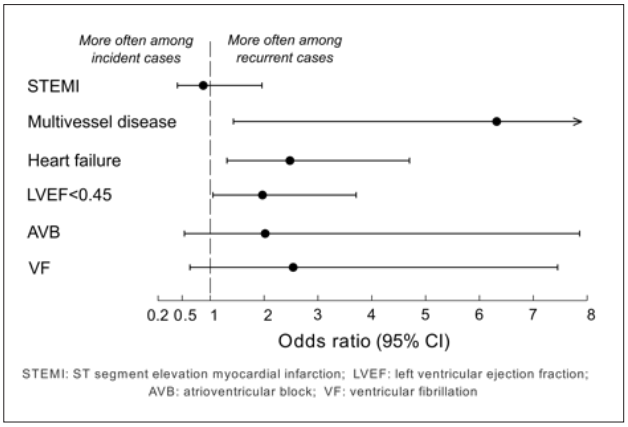

Figure 1. Differences in the clinical profile between patients hospitalized with an incident and recurrent acute myocardial infarction.

3.3 In-Hospital Treatment

The utilisation rates for beta-blockers, angiotensin-converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs), statins, and aspirin were 59.3%, 63.6%, 96.9%, and 95.1%, respectively (Table 2).

Less than half (44.4%) of the study population received all four drug classes. Only 68.5% of the patients underwent coronary angiography. Of those, 64.4% received coronary revascularisation. The proportion of patients receiving a beta-blocker or statin was lower among recurrent compared to incident cases (P=0.01 and P=0.03, respectively). No statistically significant differences in the utilisation of other drug classes or invasive diagnostic and treatment procedures were observed between the two groups.

Adjusted analyses revealed lower utilisation rates of beta-blockers among recurrent cases as compared to incident cases (OR=0.45; 95% CI: 0.24–0.85) (Figure 2).

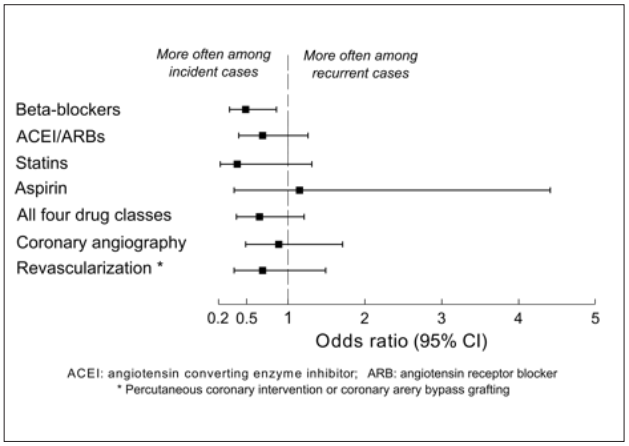

Figure 2. Differences in the in-hospital treatment between patients hospitalized with incident and recurrent acute myocardial infarction.

No statistically significant differences between groups were observed regarding ACEIs/ARBs, statins or aspirin use [(OR=0.67; 95% CI: 0.36–1.26), (OR=0.34; 95% CI: 0.12–1.31) and (OR=1.15; 95% CI: 0.30–1.31), respectively].
A similar pattern was observed in the use of invasive diagnostic and treatment procedures. No statistically significant differences between the two groups were found with regard to coronary angiography (OR=0.88; 95% CI: 0.45–1.71) or revascularisation (OR=0.67; 95% CI: 0.30–1.49).

The results of additional analyses were similar to those of the main analyses in terms of direction of the association and level of significance (Table 1, supplementary material online).

4. DISCUSSION

4.1 Main Findings

The burden of coronary risk factors in our study was very high among both incident and recurrent cases. The prevalence of HF, impaired LVEF, and multivessel CAD (all reliable indications of AMI's clinical severity) were higher among recurrent compared to incident cases. The use of evidence-based drugs in our study varied widely and, compared to incident cases, recurrent cases seemed to use less often evidence-based treatment, including revascularisation. However, the differences were statistically significant only with regard to the use of beta-blockers.

4.2 A Comparison with Other Studies

Data from a case-control study conducted in Tirana between 2003 and 2006, and enrolling 467 acute coronary syndrome (ACS) patients (i.e., a combination of AMI and unstable angina pectoris – UAP), revealed that the prevalence of obesity (BMI≥30), hypertension, DM, and current smoking were 20.6%, 29.6%, 15.8%, and 42.2%, respectively (23). Among 809 incident ACS cases admitted to CCU in Tirana in 2009, the prevalence of current smoking, hypertension, family history of CHD, and overweight/obesity were 63%, 58%, 33%, and 30%, respectively. All patients had at least two coronary risk factors (24).

Several factors may have contributed to the higher burden of coronary risk factors in our study, compared to other studies conducted in Albania (23, 24). We included in the analyses, only AMI patients, while others combined AMI and UAP patients. Further, the study by Balla et al. (24) included only incident cases, while our study population was a mixture of incident and prevalent cases. Our study population comprised severely ill patients requiring hospitalisation in CCU, whereas in the study by Burazeri et al. (23), patients were recruited from CCU and hospital wards. Despite these differences in the populations studied, a worrying increase in the burden of risk factors over time cannot be rule out, and needs further investigation.

Internationally, the prevalence of smoking, hypertension, DM, and hyperlipidaemia among 122 458 CHD patients enrolled in 14 randomised control trials was 37.9%, 43.2%, 17.5%, and 34.8%, respectively. Eighty-two percent of patients had at least one, whereas 1.0% of the cohort had all four major coronary risk factors (25). Data from the National Cardiovascular Registry (NCDR) showed that 71.4% of AMI patients reported to suffer from hypertension, and 30.5% from DM (26).

We could not identify previous publication from Albania comparing incident and recurrent cases regarding their clinical profile or in-hospital treatment. International studies have suggested that recurrent cases presented

more often with pulmonary oedema, cardiogenic shock and asystole (27), and have a higher incidence of HF (28), compared to incident cases.

The results of the analyses comparing in-hospital treatment between incident and recurrent cases have been less consistent. In the Netherlands, utilisation rates of aspirin, beta-blockers, and statins among 4718 STEMI patients were higher in incident, compared to recurrent cases (9). In the USA, similar rates were reported in incident and recurrent cases (28). With regard to revascularisation procedures, higher rates were observed in incident, compared to recurrent cases in the USA (28) and Israel (27). The direction of the association in our study suggests a more severe clinical expression of the disease with concurrent lower utilisation rates of medications in recurrent compared to incident cases. However, due to the lack of statistical significance (possibly affected by the relatively small sample size), these findings should be interpreted with caution.

A direct comparison of our findings with previously published analyses on the use of invasive procedures is challenging, as the use of these procedures is largely influenced by patients' age, gender, comorbidities, prior AMI status, and the study period – all factors that differ widely between the published studies.

4.3 Potential Mechanisms and Implications

The high burden of coronary risk factors reflects the lack of prevention measures in the population at large in Albania. Interventions aiming at reducing the burden of coronary risk factors have proven to be cost-effective (29), and can reduce CHD mortality up to 75% (30-33). Nevertheless, the majority of resources in the past 2-3 decades were allocated into tertiary care institutions, aiming at modernising the system and improving the quality of care. The observed unfavourable trends in CHD mortality in Albania, combined with our findings, point out to the immediate need for a shift in the focus of attention toward preventive measures. In 2014, health authorities launched a nationwide health campaign, inviting citizens aged 40-65 years (expanded lately to include those aged 35-70 years) to undergo a medical examination aiming at screening for CVD (with a special focus on CHD), cancer, and other relevant conditions. This was the first step in the long process of identifying the burden of coronary risk factors in the population. This campaign can lay the ground for policy and legislative changes to tackle many aspects related to diet and lifestyle, aiming at reducing the burden of risk factors and, subsequently, CHD in Albania.

Another worrying finding is the prevalence of risk factors among recurrent cases, which – with an exception of smoking – is similar to (if not higher than) that of incident cases. This reflects the failure of patients with overt CHD to change their risk profile and conduct a healthy lifestyle. Many factors may have contributed to this failure, including i) the lack of personalised recommendations upon discharge from the hospital, ii) lack of rehabilitation programs, iii) poor adherence to treatment, iv) no coordination between different actors involved in the health care system (i.e., the family doctor and specialist) during the follow up. Further studies are needed to tackle each potential component individually and provide a new insight into this phenomenon. Further, national guidelines specifying treatment goals, frequency of follow up visits and role of specialist (versus the family doctor) during the follow up are needed to optimise medical care and reduce the rate of new coronary events in this vulnerable subset of population.

Recurrent cases present with a more severe form of the disease, yet, the medication use among them tend to be suboptimal compared to that in incident cases. The reasons for these differences are not clearly explained. One hypothesis is that certain comorbidities and/or AMI complications represent contraindications to individual cardiac drugs. We addressed this issue by conducting additional analyses where we excluded patients with such comorbidities and/or AMI complications. This was associated with a slight increase in the use of beta-blockers (+ 2.4%), ACEI/ARBs (+2.4%), statins (+0.9%), and all four drug classes (+3.8%). However, the differences in the use of cardiac drugs between recurrent and incident cases did not change substantially, indicating that factors other than comorbidities might be involved.

Another reason might be related to the fact that medical staff is reluctant to perform revascularisation procedures among severely ill patients due to a poorer outcome compared to that in uncomplicated AMI cases (34).

4.4 Study Limitations

Our study has several limitations. The relatively small sample size and low number of patients with a recurrent event, is most probably responsible for the statistically non-significant findings, even though the point estimates indicate that recurrent AMIs present at the hospital with a more severe clinical expression, and underutilise the recommended drug classes compared to incident AMIs.

Our sample size did not allow us to explore the role of medications taken prior to hospitalisation on the burden of risk factors, either. Furthermore, we could not determine the proportion of patients with controlled level of risk factors. In addition, we did not know the proportion of patients who might have been scheduled to receive revascularisation upon AMI discharge, as follow-up information was not available. We therefore restricted our focus on treatment during MI hospitalization. The

distinction between 'never' and 'former' smokers was not available in our study. Consequently, we could not discriminate between patients who smoked and gave up smoking, and those who never smoked. This distinction would have been of particular interest among recurrent cases. We also lacked information on the time from symptom onset to arrival at the hospital; an important factor influencing the decision to perform coronary angiography and revascularisation.

5 CONCLUSIONS

Recurrent cases seemed to be admitted with a more severe clinical form of AMI and received optimal treatment less often, compared to incident cases. A more aggressive treatment approach combined with the implementation of preventive strategies would help improving the prognosis of patients suffering a recurrent AMI.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

None

ETHICAL APPROVAL

The study was approved by the National Committee for Bio-Medical Ethics in Albania.

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SELF-REPORTED HYPOGLYCAEMIA IN PATIENTS TREATED WITH INSULIN: A LARGE SLOVENIAN RETROSPECTIVELY-PROSPECTIVE STUDY

HIPOGLIKEMIJE PRI BOLNIKIH, ZDRAVLJENIH Z INSULINOM: VELIKA SLOVENSKA RETROSPEKTIVNOPROSPEKTIVNA RAZISKAVA

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ABSTRACT

Introduction. Hypoglycaemia is the major barrier for glycaemic target achievement in patients treated with insulin. The aim of the present study was to investigate real-world incidence and predictors of hypoglycaemia in insulin-treated patients.

Methods. More than 300 consecutive patients with type 1 or type 2 diabetes treated with insulin were enrolled during regular out-patient visits from 36 diabetes practices throughout the whole country. They completed a comprehensive questionnaire on hypoglycaemia knowledge, awareness, and incidence in the last month and last six months. In addition, in the prospective part, patients recorded incidence of hypoglycaemic events using a special diary prospectively on a daily basis, through 4 weeks.

Results. At least one hypoglycaemic event was self-reported in 84.1%, and 56.4% of patients with type 1 and type 2 diabetes, respectively, during the prospective period of 4 weeks. 43.4% and 26.2% of patients with type 1 and type 2 diabetes, respectively, experienced a nocturnal hypoglycaemic event. In the same time-period, severe hypoglycaemia was experienced by 15.9% and 7.1% of patients with type 1 and type 2 diabetes, respectively. Lower glycated haemoglobin was not a significant predictor of hypoglycaemia.

Conclusions. Rates of self-reported hypoglycaemia in patients treated with insulin in the largest and most comprehensive study in Slovenia so far are higher than reported from randomised control trials, but comparable to data from observational studies. Hypoglycaemia incidence was high even with high glycated haemoglobin values.

Keywords:
hypoglycaemia, type 1 diabetes, type 2 diabetes, insulin treatment, Slovenia

IZVLEČEK

***Uvod**. Hipoglikemije so glavni omejujoči dejavnik varnega doseganja glikemičnih ciljev pri bolnikih s sladkorno boleznijo, ki se zdravijo z insulinom. Namen te raziskave je bil raziskati pojavnost hipoglikemij in napovedne dejavnike hipoglikemij v vsakodnevnem življenju bolnikov s sladkorno boleznijo.*

***Metode**. V raziskavo smo vključili več kot 300 zaporednih bolnikov s sladkorno boleznijo tipa 1 ali 2, zdravljenih z insulinom, iz 36 diabetoloških ambulant po državi. Bolniki so izpolnili natančen vprašalnik, ki je poizvedoval o znanju o hipoglikemijah, njihovemu zaznavanju in pojavnosti v zadnjem mesecu in v zadnjih šestih mesecih. V nadaljevalnem, prospektivnem delu raziskave, ki je trajal 1 mesec, so bolniki vsakodnevno beležili dnevnik hipoglikemij, kamor so sproti vpisovali, ali so doživeli hipoglikemijo.*

***Rezultati**. V raziskavo je bilo vključenih 84 bolnikov s sladkorno boleznijo tipa 1 in 227 bolnikov s sladkorno boleznijo tipa 2. Med enomesečnim prospektivnim delom raziskave je 84,1% bolnikov s sladkorno boleznijo tipa 1 in 56,4% bolnikov s sladkorno boleznijo tipa 2 poročalo, da so doživeli vsaj eno hipoglikemijo. Nočno hipoglikemijo je doživelo 43,4% bolnikov s sladkorno boleznijo tipa 1 in 26,2% bolnikov s sladkorno boleznijo tipa 2. Hudo hipoglikemijo je doživelo 15,9 % bolnikov s sladkorno boleznijo tipa 1 in 7,1% bolnikov s sladkorno boleznijo tipa 2. Nižji glikiran hemoglobin ni bil napovedni dejavnik za pojav hipoglikemij.*

***Zaključki**. Incidenca hipoglikemij, o katerih so poročali sami bolniki, zdravljeni z insulinom, je v doslej največji raziskavi o hipoglikemijah na Slovenskem višja kot v velikih randomiziranih prospektivnih raziskavah, a primerljiva kot v podobnih opazovalnih raziskavah iz vsakodnevnega življenja. Incidenca hipoglikemij je visoka tudi pri bolnikih z visokim glikiranim hemoglobinom.*

Ključne besede:
hipoglikemija, sladkorna bolezen tipa 1, sladkorna bolezen tipa 2, insulinsko zdravljenje, Slovenija

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1 INTRODUCTION

Intensive hyperglycaemia treatment reduces the risk of development of chronic diabetes complications. However, the main obstacle to attain tight glycaemic goals is the risk of hypoglycaemia (1). In addition, experiencing hypoglycaemia, especially a nocturnal one, decreases quality of life substantially (2). Moreover, severe hypoglycaemia, requiring external assistance for recovery, was associated with increased cardiovascular and overall mortality (3).

Data on hypoglycaemia incidence are variable, mainly because of the lack of a single threshold plasma glucose concentration that defines hypoglycaemia in diabetes. Typically, it is believed that hypoglycaemia incidence is high in type 1 diabetes, but not in type 2 diabetes. Yet, incidence of hypoglycaemia increases with type 2 diabetes duration (4, 5). Reported incidence of severe hypoglycaemia in retrospective observational studies in patients with longstanding type 1 diabetes was 320 cases per 100 patient-years (6). Of note, substantially lower incidence was established from a prospective randomised DCCT trial, with 62 cases per 100 patient-years (7). On the other hand, in patients with type 2 diabetes, severe hypoglycaemia incidence was 70 per 100 patient-years in observational studies (6), whereas it was only 3.1 per 100 patient-years in a multicentre, prospective, randomised ACCORD study (8).

Hypoglycaemia incidence in patients treated with insulin in Slovenia was never systematically studied. Therefore, the aim of the present study was to assess hypoglycaemia incidence in insulin-treated patients with type 1 and type 2 diabetes mellitus as patients report it, and to investigate factors, associated with hypoglycaemia risk.

2 METHODS

This was a multicentre, non-interventional study, designed to assess hypoglycaemia incidence in patients with type 1 and type 2 diabetes, treated with insulin. The study protocol, with hypoglycaemia classification and statistical analyses was in detail described elsewhere (9).

During the routine, out-patient visits with diabetologists, from 474 consecutive patients from 36 clinical sites in Slovenia invited to participate, 311 were enrolled in the study. The sites were quite uniformly distributed throughout Slovenia. The biggest number of patients was recruited from the north-western Slovenia, the only region without any patients included was the Slovenj Gradec region. The average number of patients per site was 8.6, per region 39. Minimal number of patients per region was 10 (Murska Sobota), maximal 75 (Gorenjska). Patients included were more than 18 years old, had type 1 or type 2 diabetes mellitus, with at least 12 months of insulin treatment experience, and had signed the informed consent. The exclusion criterion was the inability to complete a written questionnaire and a hypoglycaemia diary. Patients were not given any financial payment for the participation in the study.

Baseline characteristics of the patients analysed are presented in Table 1. More than two thirds of patients had type 2 diabetes mellitus.

Table 1. Baseline characteristics of patients included.

	DM type 1 N=84	DM type 2 N=227
Age (years)	49±13	64±10
Gender (male/female, %)	57/43	62/38
Diabetes duration (years)	21±11	16±9
Insulin therapy duration (years)	19±12	6 (3, 10)*
HbA1c (%)	9.2±2.7	9.3±2.8
Employed/unemployed/retired/other (%)	65/5/28/12	15/8/75/2
Diabetes treatment		
Short-acting insulin	85.7	48.9
Long-acting insulin	60.7	63.1
Pre-mixed insulin	1.2	35.1
Oral therapy	4.8	24.9
Injectable non-insulin therapy	3.6	10.2
Insulin pump	32.1	4.9
Self-measurement of blood glucose (%)	98.8	99.6
Continuous glucose measurement (%)	34.2	38.4
Hypoglycaemia experience (%)	98.8	89.2

*Non-normally distributed variables are represented as median (25th, 75th percentile)

The study was comprised of two parts: a retrospective 6-month period and a prospective 4-week period. In the retrospective part, patients were asked to recall a 6-month history of severe hypoglycaemia and a 4-week history of non-severe and severe hypoglycaemia. In the prospective period, they were asked to complete a special diary of hypoglycaemia on a daily basis.

The primary endpoint of the study was the percentage of patients experiencing at least one hypoglycaemic event during the 4-week follow-up period. The majority of statistical analyses were prepared on data from the prospective part, in order to avoid a recall bias.

The study was performed from March to September 2013. It was conducted in accordance with the Declaration of Helsinki and was also approved by the Slovenian Ethics Committee.

2.1 Statistical Analyses

The majority of analyses were descriptive in nature. All statistical tests were two-sided. A p-value of less than

0.05 was considered as statistically significant. Univariate binomial regression models were used to examine the relationship between hypoglycaemia and factors, including age, gender, HbA1c at baseline, diabetes duration, duration of insulin therapy, type of insulin therapy, frequency of blood glucose monitoring, knowledge of hypoglycaemia, hypoglycaemia unawareness, fear of hypoglycaemia, period, and diabetes type. Differences in retrospective versus prospective data reporting were assessed using a paired t-test.

Definitions used: non-severe hypoglycaemia was defined as a hypoglycaemic event managed by the patient alone, whereas severe hypoglycaemia was defined as any hypoglycaemic event that requires external assistance for recovery. Nocturnal hypoglycaemia was defined as a hypoglycaemic event occurring between midnight and 6 in the morning. Documented symptomatic hypoglycaemia was defined as any event reported by the patient as a symptomatic hypoglycaemia, regardless of the glucose level. Patients who answered the question 'Do you have symptoms when you have a low blood sugar measurement?' with 'never' or 'occasionally,' were said to have 'severely impaired' or 'impaired' hypoglycaemia awareness, respectively.

3 RESULTS

Ninety-nine % of patients with type 1 diabetes and 89% of patients with type 2 diabetes reported that they had experienced hypoglycaemia in their life. In addition, 30% of patients with type 1 diabetes and 27% of patients with type 2 diabetes reported impaired or severely impaired hypoglycaemia awareness.

At least one hypoglycaemic event (with or without measured glucose value) was self-reported in 84.1% and 56.4% of patients with type 1 and type 2 diabetes, respectively, during the prospective period of 4 weeks. 43.4% and 26.2% of patients with type 1 and type 2 diabetes, respectively, experienced a nocturnal hypoglycaemic event. In the same time-period severe hypoglycaemia was experienced by 15.9% and 7.1% of patients with type 1 and type 2 diabetes, respectively.

Estimated annual incidence rate of documented symptomatic hypoglycaemic events (with blood glucose 3.9 mmol/l or less), calculated from patient diaries in the prospective follow-up was 48 events (95% CI 43 to 53) and 11 events (95% CI 9 to 13) per patient-year in type 1 and type 2 diabetes, respectively. Also, estimated annual incidence rate of severe hypoglycaemia was 6 events (95% CI 4 to 8) and 1 event (95% CI 1 to 2) per patient-year in type 1 and type 2 diabetes, respectively. There were altogether 62 episodes of severe hypoglycaemia documented in 4 weeks period in 29 patients with type 1 and type 2 diabetes. Compared to type 2 diabetes, the percentage of patients experiencing severe hypoglycaemia was more than double in type 1 diabetes. Nocturnal hypoglycaemia was reported with an estimated annual rate 12 (95% CI 9 to 15) and 8 (95% CI 5 to 8) patient-years in type 1 and type 2 diabetes, respectively.

When asked about their definition of hypoglycaemia, only 40% of type 1 and of type 2 diabetes patients define hypoglycaemia depending on both, blood glucose measurement and symptoms, whereas 33% of type 1 and 37% of type 2 diabetes patients define hypoglycaemia only depending on the presence of symptoms. The mean blood glucose value below, which patients considered a glucose value to be a marker of hypoglycaemia, was 3.18 ±0.64 mmol/l and 3.41±0.83 mmol/l in type 1 diabetes and type 2 diabetes, respectively.

Differences on hypoglycaemia recall were noted when data on hypoglycaemia from the prospective and retrospective part of the study were compared, depending on diabetes type (Figure 1). Specifically, a large difference in recall was noted in the case of mild hypoglycaemia in type 1 diabetes patients, with significantly less hypoglycaemias reported by the patients from the past 4 weeks compared to prospective 4 weeks (37 vs.77 cases, p<0.001). There was a much smaller, but still statistically significant difference seen in type 2 diabetes, and mild hypoglycaemia reporting, with lower reporting for the past 4 weeks, compared to the prospective reporting (18 vs. 24 cases, p=0.027). Of note, in type 2 diabetes, there was also a difference in nocturnal hypoglycaemia reporting, but in the opposite direction, reporting more nocturnal hypoglycaemia in a retrospective time period (12 vs.6 cases, p=0.007).

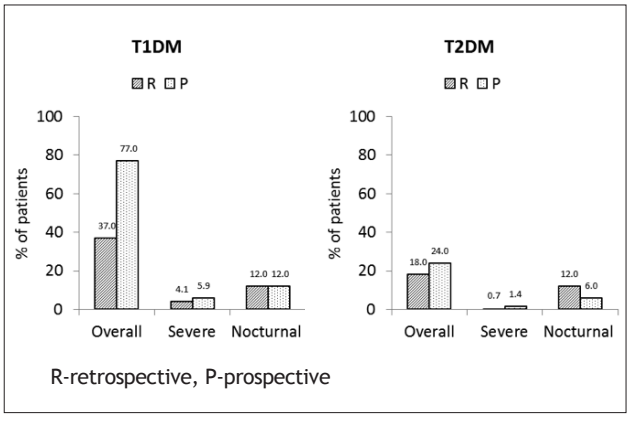

Figure 1. Hypoglycaemia incidence depending on the retrospective or prospective recall by patients.

Using a negative binomial model, adjusted for several factors, including duration of diabetes, age, hypoglycaemia awareness, and type of insulin therapy, we studied possible predictors of hypoglycaemia incidence. From all the variables studied, only fear of hypoglycaemia predicted severe hypoglycaemia incidence. Neither HbA1c, age, diabetes duration nor hypoglycaemia awareness were predictors of severe hypoglycaemia (Figure 2, Table 2).

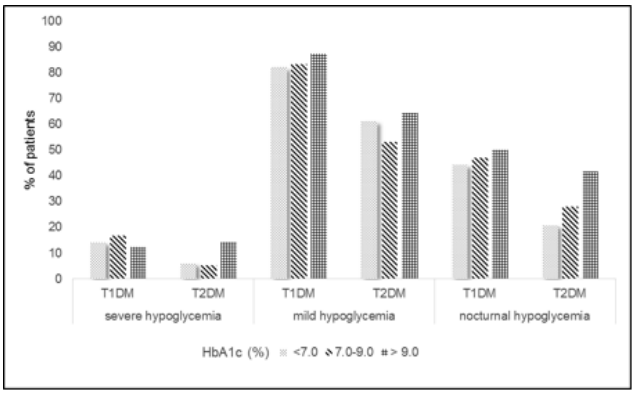

Figure 2. Hypoglycaemia incidence and HbA1c.

Table 2. Predictors of severe hypoglycaemia in a fully adjusted negative binomial model.

VARIABLES	HR	95% C.I.	P-VALUE
Age (years)	0.99	0.96, 1.02	0.556
Female gender	0.80	0.36, 1.78	0.585
HbA1c (%)	1.01	0.98, 1.04	0.441
Diabetes duration (years)	1.02	0.94, 1.11	0.594
Type of insulin therapy			
Short-acting (reference)	-	-	-
Long-acting	0.54	0.10, 3.07	0.489
Long and short-acting	0.70	0.21, 2.28	0.550
Mixed	NC	NC	NC
Other	0.36	0.08, 1.57	0.175
Blood glucose testing (per day)	1.08	0.84, 1.38	0.555
Hypoglycaemia unawareness	1.00	0.44, 2.24	0.996
Fear of hypoglycaemia	1.20	1.05, 1.37	0.009
Diabetes type 2	0.72	0.20, 2.67	0.627

NC-not calculable. Model adjusted for: age, gender, HbA1c at baseline, duration of diabetes, duration of insulin therapy, type of Insulin therapy, frequency of blood glucose monitoring, knowledge of hypoglycaemia, hypoglycaemia unawareness, fear of hypoglycaemia, period, diabetes type.

After experiencing hypoglycaemia in the prospective 4 weeks of the study, patient actions differed substantially between Type 1 and Type 2 diabetes, as represented in Figure 3.

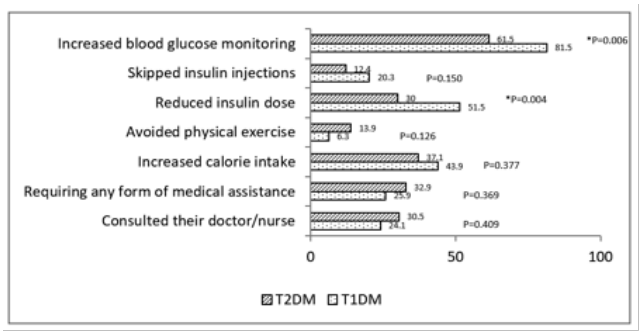

Figure 3. Actions resulting from hypoglycaemia in patients with Type 1 and Type 2 diabetes. (Statistically significant differences are marked with *).

4 DISCUSSION

This is the first study that reports hypoglycaemia incidence in a large cohort of insulin-treated patients with type 1 and type 2 diabetes mellitus in Slovenia. The self-reported rates of hypoglycaemia in this study are substantially higher than previously observed in other studies, especially in randomised controlled trials.

Hypoglycaemia is considered a major obstacle for optimal glycaemic control achievement in insulin-treated patients with diabetes. Moreover, a severe hypoglycaemia is strongly associated with a series of negative outcomes, including the increased risk of a major macrovascular event, as well as the increased risk of a cardiovascular or non-cardiovascular death (3,10). Therefore, prevention of severe hypoglycaemia is of central importance in delivering care to insulin-treated patients with diabetes. Interestingly, severe hypoglycaemia could not be predicted in our patients by any measured factor, including gender, diabetes duration, HbA1c, age, frequency of blood glucose measurement, or type of insulin therapy. The only factor that was significantly and independently associated with severe hypoglycaemia incidence in the fully adjusted multivariate model was greater fear of hypoglycaemia. Although from our model we cannot conclude that greater fear of hypoglycaemia was the direct consequence of severe hypoglycaemia experience in the past, it is the possible explanation, and in line with other studies (11, 12). Even more importantly, recognising fear of hypoglycaemia as a predictor of future severe hypoglycaemia gives us an important message – that addressing that fear by a tailored education we could potentially avoid severe hypoglycaemia.

The incidence of non-severe hypoglycaemia is not easily assessed in everyday life of insulin-treated patients, which is at least partly due to different levels of hypoglycaemia awareness. However, data on severe hypoglycaemia incidence is much more reliable (13). Nonetheless, in our study, severe hypoglycaemia incidence in type 2 diabetes was more than 20-times greater than, for example, in the ACCORD study (8), and more than 10-times greater than in the observational UK Hypoglycaemia study (6). In type 1 diabetes, on the other hand, difference in severe hypoglycaemia rate was smaller, but still 10-times higher in our study compared to the intensive arm of the DCCT trial (14), and almost 2-times higher compared to the UK Hypoglycaemia study (6). Not surprisingly, our data are very near to other real-world patient cohort studies (12, 15). Such a pronounced difference in hypoglycaemia incidence is likely due to the nature of the studies and study methodology. In other words,, results of our study reflect data on patients from the everyday practice, whereas patients with concomitant diseases, recurrent hypoglycaemia, or hypoglycaemia unawareness are usually excluded from randomised controlled trials. In addition, the incidence of severe hypoglycaemia was self-reported in our study, as experienced by the patients, and was not confirmed by means of patient medical files. Moreover, our patient population, especially with type 2 diabetes, was rather older and had, on average, diabetes for a substantially longer time period, compared to similar studies. The other important fact is also that the definitions of hypoglycaemia changed over the last years, even in the last few years (13, 16); however, the findings of our study go beyond the definitions and reveal what patients consider relevant for their everyday life with insulin.

However, comparing results from the Slovenian cohort to the recently published results of the study analysing hypoglycaemia incidence in more than 27,000 patients globally (9), the incidence of severe hypoglycemia in Slovenian type 1 diabetes was higher (5.9 vs. 4.9 events-patient-year) and in type 2 diabetes was lower (1.5 vs. 2.5 events-patient-year). The incidence of nocturnal hypoglycaemia in type 1 diabetes was similar in Slovenia and globally, whereas in type 2 diabetes, it was almost twice as common as elsewhere (6.4 vs. 3.67 events-patient-year) (9). Data on nocturnal hypoglycaemia is quite of a concern. Firstly, nocturnal hypoglycaemias can lead to sleep deprivation, lower quality of life, lower work performance, worse driving skills, etc. (17). Secondly, nocturnal hypoglycaemias are characterised by the lower intensity and recognizability of counterregulatory responses, thereby depriving individuals of the adequate stimulus to counteract hypoglycaemia. Therefore, nocturnal hypoglycaemias can pass by unrecognized and lead to lower hypoglycaemia awareness (18). Lastly, awakening response after nocturnal hypoglycaemia is lower and may affect the patient's ability to intake adequate amount of carbohydrates, especially in elderly people with possibly pre-existing cognitive impairment (17).

In type 1 diabetes, comparing prospective hypoglycaemia count with a retrospective recall, we detect a large discrepancy, especially in mild hypoglycaemia. Because it is a frequent event, patients probably consider it normal and devote less attention to it. However, the way the mild hypoglycaemia is perceived might be crucial to prevent hypoglycaemia desensitisation and even hypoglycaemia unawareness, often stemming from repetitive hypoglycaemia (19). A similar trend in mild hypoglycaemia was seen in our type 2 diabetes patients. However, in this group, reported past incidence of nocturnal hypoglycaemia was higher than in the prospective part of the study, possibly indicating that experience of nocturnal hypoglycaemia is more stressful than day hypoglycaemia, and leads to oversizing its appearance. Nocturnal hypoglycaemia, in particular, impacts one's sense of well-being because of its impact on sleep quality and quantity (20). Fear of hypoglycaemia, especially nocturnal one, may be one of the important reasons patients rather choose higher glycaemic targets (21).

From the DCCT trial, the association between lower HbA1c and higher hypoglycaemia incidence is well established (22). Yet, the results of our study underline that higher HbA1c values are not protective from experiencing hypoglycaemia, since hypoglycaemia was reported with similar frequency with low as well as with high levels of glycated haemoglobin. The association is easily understood with low levels of glycated haemoglobin, since frequent hypoglycaemias lower average glucose levels. On the other hand, it may be quite surprising to see that hypoglycaemias are no less frequent in patients with high glycated haemoglobin values. A possible explanation could be that patients experiencing hypoglycaemia deliberately lower insulin dose, as also reported in Figure 3 in our cohort of patients, or maybe even skip insulin application (23).

In our study, a very high average glycated haemoglobin value was reported, even substantially higher from the global report of the same study (9). If this value holds true, it is very alarming for the diabetes patient care in Slovenia, and definitely deserves further assessments. However, due to the study design, where data were not captured by patient medical files, but rather by a patient recall, there is a possibility that patients reported values of average plasma glucose concentration rather than glycated haemoglobin percentages. Similarly, we explain a very high reported percentage of continuous glucose monitoring usage in type 2 diabetes with misunderstanding of the meaning of the question. Furthermore, in this

study, we did not collect data on education level, which is, together with low socioeconomic status, a very well recognised factor associated with higher hypoglycaemia risk in patients with diabetes (13, 24, 25). This patient population could also comprise a large part of the group of non-responders. Unfortunately, we do not have exact data on them, since they did not complete any questionnaire. We observed that the non-respondent population is of two categories. One is a working population, which did not decide to participate in the study due to lack of time. For this group, we expect it to be of younger age and not to have increased the number of overall hypoglycaemia incidence. The second group is a group of patients who could not be included because of illiteracy or other issues resulting in the inability to complete the written questionnaire, like vision impairment and the lack of language understanding. We expect this group of patients to be even more vulnerable to hypoglycaemia and, if included, would be expected to further increase hypoglycaemia incidence reported in the study.

Despite some limitations of the design of the present study, this study design gives unique insights into the issue of hypoglycaemia through patient experience. In this way, new strategies can be employed that address this iatrogenic diabetes treatment complication more efficiently. Firstly, at the patient and the patient organisations level, the awareness of hypoglycaemia incidence should be raised, and instructions on the ways to decrease their occurrence should be given in a number of different formats, including visual and auditory message modes. In addition, fear of hypoglycaemia as a predictor of severe hypoglycaemia should be further addressed in the future studies as well as in routine clinical practice. Diabetes educators and medical doctors should become even more sensitised to the issue of high hypoglycaemia incidence, accurately assess it at every patient visit, and learn about the ways patients engage with them. Moreover, development of new treatment modules that include cognitive restructuring for addressing fear of hypoglycaemia should be welcomed. Furthermore, research with innovative methodological approach (26) and deep understanding of possibly preventable socioeconomic inequalities (27) could lead to a creation of patient-tailored, most probably region-specific approaches to deliver the maximally efficient education on hypoglycaemia for its prevention.

5 CONCLUSIONS

In conclusion, our study is the first comprehensive report on patient-reported hypoglycaemia incidence in Slovenian insulin-treated type 1 and type 2 diabetes patients that highlights several important aspects. Firstly, the incidence of hypoglycaemia, especially severe ones, is substantially higher than the ones reported from randomised controlled trials. Secondly, higher glycated haemoglobin values do not exclude high hypoglycaemia event rate. Thirdly, nocturnal hypoglycaemia needs special consideration in everyday management of insulin-treated patients, especially type 2. Fourthly, since factors associated with hypoglycaemia remained largely unidentified, especially in the context of the socioeconomic status, such as education level, addressing hypoglycaemia efficiently in the future calls for a much broader mixed research method approach, including qualitative research.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The study was approved by the Slovenian Ethics Committee, reference number 116/02/13.

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SELF- PERCEIVED STRESS IN RELATION TO ANXIETY, DEPRESSION AND HEALTH-RELATED QUALITY OF LIFE AMONG HEALTH PROFESSIONS STUDENTS: A CROSS-SECTIONAL STUDY FROM BOSNIA AND HERZEGOVINA

SAMO-ZAZNAVA STRESA V POVEZAVI Z ANKSIOZNOSTJO, DEPRESIJO IN Z ZDRAVJEM POVEZANO KAKOVOSTJO ŽIVLJENJA MED ŠTUDENTI ZDRAVSTVENIH VED: PRESEČNA ŠTUDIJA IZ BOSNE IN HERCEGOVINE

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ABSTRACT

Introduction. The purpose of the present study was to examine self-perceived stress of health professions students at the Faculty of Medicine Foča, and to explore its association with anxiety, depression and health-related quality of life.

Methods. The cross-sectional study enrolled 451 students at the Faculty of Medicine (medicine, dentistry, nursing and speech therapy). Survey instruments were distributed at the conclusion of the spring semester during the last required lecture for each year and study programme class. Perceived stress was assessed using the 14-item Perceived Stress Scale. The students were evaluated for symptoms of depression and anxiety, using Zung's self-assessment inventory for depression and the Spielberger State-Trait Anxiety Inventory (STAI). European Quality of Life-5 dimensions were used for describing and evaluating health. Multivariate analyses were carried out using logistic regression to examine the relationship between the outcome variable and selected determinant factors.

Results. A high degree of stress was reported by 1.6% of students, while the majority of students had either moderate (70.6%) or low degree (27.5%) of stress. The significant independent factors associated with perceived stress were anxiety score (OR, 0.339; CI 95%, 0.276-0.403) and EQ-5D score (OR, 0.044; CI 95%, 0.033-0.085). A high degree of perceived stress (OR, 0.624; CI 95%, 0.507-0.704), the presence of depression (OR, 0.800; CI 95%, 0.513-1.087), and low quality of life were associated with anxiety (OR, 0.073; CI 95%, 0.018-0.128).

Conclusion. Higher levels of perceived stress predispose health professions students for anxiety and lower quality of life. The study programme was not a significant determinant of perceived stress sore.

Keywords:
assessment, stress, anxiety, students, quality of life

IZVLEČEK

***Uvod**. Namen študije je bil preučiti samo-zaznan stres študentov zdravstvenih ved na Medicinski fakulteti Foča in raziskati njegovo povezavo z anksioznostjo, depresijo in z zdravjem povezano kakovostjo življenja.*

***Metode**. Presečna študija je vključevala 451 študentov Medicinske fakultete (medicina, zobozdravstvo, zdravstvena nega in govorna terapija). Raziskovalna orodja so bila razdeljena ob koncu spomladanskega semestra med zadnjimi obveznimi predavanji za vsak letnik in študijski program. Zaznan stres je bil ocenjen z uporabo 14-stopenjske lestvice za zaznavanje stresa. Med študenti smo ocenili simptome depresije in aksioznosti z uporabo Zungovega vprašalnika za samooceno depresije in orodja Spielbergerjevega vprašalnika za oceno anksioznosti (STAI). Za opis in vrednotenje zdravja so bili uporabljeni vprašalniki o kakovosti življenja EQ-5D. Za proučevanje povezav med spremenljivko izidov in izbranimi determinantami so bile izvedene multivariatne analize z uporabo logistične represije.*

***Rezultati**. O visoki stopnji stresa je poročalo 1,6% študentov, medtem ko je večina študentov poročala o srednji (70,6%) ali nizki (27,5%) stopnji stresa. Pomembni neodvisni dejavniki, ki so bili povezani z zaznavanjem stresa, so bili rezultati vprašalnika o anksioznosti (OR 0,339; CI 95%, 0,276-0,403) in rezultati vprašalnika EQ-5D (OR 0,044; CI 95%, 0,033-0,085). Visoke stopnje zaznanega stresa (OR 0,624; CI 95%, 0,507-0,704), prisotnost depresije (OR 0,800; CI 95%, 0,513-1,087) in slaba kakovost življenja so bili povezani z anksioznostjo (OR 0,073; CI 95%, 0,018-0,128).*

***Zaključek**. Višje stopnje zaznanega stresa so predispozicija za anksioznost in nižjo kakovost življenja študentov zdravstvenih ved. Študijski program ni bil bistvena determinanta za zaznavanje stopnje stresa.*

***Ključne besede**:*
ocena, stres, anksioznost, študenti, kakovost življenja

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1 INTRODUCTION

The beginning of university life represents an important period of transition from adolescence to young adulthood that could be very often difficult due to interactions between individual psychological characteristics and common stressors, such as academic demands, changes in lifestyle, moving away from home, separating from family, inadequate living conditions, physical and emotional problems, and financial concerns (1-3). Stress in university students may also be related to examination (4), pressure of expectation to succeed or to be competitive, and an uncertain future (5, 6). Numerous studies analysed the correlation between exposure to aforementioned stressors and students' health (7, 8). It has been shown that stress has a significant, negative impact on overall health (7-9) and may cause mental problems, deleterious dietary changes (10) as well as generate poor coping skills leading to aggressive behaviour and somatic disorders (11).

Although it is not well-known whether health professions education differs from other higher education, it is generally considered as highly demanding, and students perceive it as a source of significant psychological and emotional distress (12-20).

Previous studies have shown that students who chose medical profession because they wish to help people have greater predisposition to the stress over the students driven by professional respect or material benefit (21). Besides being exposed to academic-related stress, caused by curriculum overload, constant assessments, little time available or variable hour shift for clinical rotations (22), health professions students also encounter occupational stress because they deal with people, their health and their lives. In order to reach the personal and professional maturity the health professions jobs require, the students partake of handling their own mind, attitudes or emotions, and coping with the stress in different, sometimes even difficult, clinical situations (23). Inadequate teaching methods or lack of mentor's support often unable students to adopt required skills, empathy and professionalism manners, ultimately leading to poor coping mechanisms and greater proneness to stress (24).

Increased perception of stress might be associated with moderate level of anxiety, depression symptoms, interpersonal sensitivity, frustration and powerlessness (25). When associated with anxiety and depression, occupational stress, as experienced by the student, can influence his or her quality of life and decrease his or her academic performance due to anxiety-induced difficult cognitive functioning, such as memory disorders, blockage, incapacity to make decisions, and increased sensitivity to appraisals of others (26, 27). Previous research found that the students and residents who frequently experience stress, also exhibit higher degree of burnout (20, 28) and future professional impairment (29).

As a psychological and physiological state, anxiety is considered to be a normal response to stress, but prolonged exposure and higher levels of perceived stress may lead to adverse consequences, including the development of anxiety disorder (30). When experiencing high levels of anxiety during their studies, the students are frequently inclined to achieve lower quality of total performance, which usually makes them feel that the situational demands exceed their competences, which further deepens perceived stress, ultimately resulting in the individual's psychological distress (31). Situational stress, showed to be a factor that elevates state anxiety, probably because students realise that they will be judged and that their achievements will be compared with the achievements of others. Highly trait-anxious students often experienced stronger state-anxiety compared to low trait-anxious students, which implies that students with anxiety tendencies are more predisposed to state anxiety in stressful situation (32).

Very little is known about perceived stress among health professions students in Bosnia and Herzegovina (BiH), especially students of medicine. At the Faculty of Medicine, University of East Sarajevo, the study programme of medicine still has traditional curriculum. The students begin their training with three years of pre-clinical course, involving the basic medical sciences. This is followed by the three years of clinical courses and clinical rotations. Students attend lectures on all aspects of medical practice during the whole training. The programme is considered demanding, but up to now, aspects of study stress and generally students' health and behaviour have not yet been studied much (33).

The purpose of the present study was to examine perceived stress of students at the Faculty of Medicine Foča, and to explore its association with anxiety, depression, and health-related quality of life. The questions were formulated into the following hypothesis. The symptoms of depression and anxiety among undergraduate students are associated with perceived stress and self-perceived health. The perceived stress in students of medicine differs from that in the students of similar study programmes, such as dentistry, nursing, and speech language therapy.

2 METHODS

2.1 Study Design and Participants

The cross-sectional study was conducted in June 2015. Data were collected from 18-year-old students or older enrolled in one of four study programmes at the Faculty of Medicine (medicine, dentistry, nursing, speech therapy). All first-year through sixth-year students (fourth-year for nursing and speech therapy) were invited to participate in the study. Survey instruments were distributed at the conclusion of the spring semester during the last required

lecture for each year and study programme class. The study was extensively introduced to students by research assistants. It was explained that the refusal to participate in the survey would have no academic consequences. Each student received a short description of research objectives and paper-and-pencil survey instruments. The survey instruments took approximately 15 minutes to complete. Responses were anonymous, but survey instruments and questionnaires were numbered and collated for data analysis.

Students were informed that by completing the questionnaire, they agreed to participate in the study. No incentives were provided.

Out of the total 640 invited students, 451 agreed to participate in the survey and complete questionnaires (response rate was 70.5%). Twenty-five students were excluded from the analysis due to incompletely filled out questionnaire. Therefore, the final sample consisted of 426 students.

The study was conducted according to the principles of the Declaration of Helsinki.

2.2 Instruments

Age, gender, place of birth, financial status and social support were surveyed for social background.

Perceived stress was assessed using the 14-item Perceived Stress Scale (PSS) (34). The PSS consists of multiple choice questions and measures stressful experiences and responses to stress over the previous 4 weeks. Items used a 4-point Likert scale response format, ranging from 'never' (0) to 'very often' (4). Questions that relate negative events or responses were scored in reverse manner. Scores were obtained by averaging their responses to all the items of the scale. The results of the scores were compared with scores predetermined for the questionnaire, and were classified as low (15-28), moderate (29-42), and high degree of stress (>43). Bosnian translation of the PSS was performed employing two independent interpreters. For both translations, cases of disagreement were resolved by the appropriate researchers, who were native speakers in Bosnian and had expertise in research methodology. Cronbach alpha value of 0.82 for PSS was found to be adequate.

For the assessment of depressive symptoms, the Zung self-rating depression scale was used. The scale consists of 20 questions that should be answered according to 4 statements (most of the time/always/rarely/never). The composite score ranges from 20 to 80 points. The results were compared with scores predetermined for the questionnaire, classifying depressive symptoms as mild (45 to 59 points); moderate (60-69 points); and severe (≥70). The score ranging from 20 to 44 was considered normal (35).

The Spielberger State-Trait Anxiety Inventory (STAI) was used to evaluate anxiety symptoms. The STAI is composed of two different scales: one related to state anxiety (STAI-S) and the other to trait anxiety (STAI-T). The State Anxiety Scale evaluated a transitory emotional state characterised by subjective feelings that may vary in intensity over time (transient manifest feelings of insecurity.). The Trait Anxiety Scale measured anxiety proneness and tendency to perceive a wider range of situations as threatening (personality characteristic). There are 20 items in each scale that are answered on a 4-point Likert scale (36). Two subscales were scored separately. The results of the scores were compared with scores predetermined for the questionnaire, classifying the anxiety levels as low (20 to 34 points); moderate (35-49 points); and high/serious (≥50).

European Quality of Life-5 dimensions (EQ-5D) was used for describing and evaluating health (37). The first part of EQ-5D describes five dimensions, namely: 1) mobility, 2) self-care, 3) usual activity, 4) pain/discomfort, and 5) anxiety/depression. For each dimension, there are three categories of answers; no problem (0), some problems (1) and severe problems (2). The composite score ranges from 0 to 10 points. The EQ Visual Analogue Scale (EQ-5D VAS) was used as a measure of general self-assessment of Health-Related Quality of Life (HRQoL). The students were asked to circle the best answers that apply to them on the scale from 0 (the worst health imaginable) to 100 (the best health imaginable).

2.3 Statistical Analysis

Data analysis was performed using the Software Package for Statistical Analysis – The IBM SPSS 21 (Chicago, IL, 2012). Differences between more than two groups were calculated using ANOVA. Multivariate analyses were carried out using logistic regression to examine the relationship between the outcome variable and selected determinant factors. Unadjusted odds ratios (OR) and their 95% confidence intervals (CI) were used as indicators of the strength of association. A p-value of 0.05 or less was used as the cut-off level for statistical significance.

3 RESULTS

The study involved 426 students with the mean age of 21.5±2.26 years. Most students were female (69.2%), born in an urban place (75.8%), and had good financial status (86.9%).

A high degree of stress was reported by 1.6% of students, while the majority of students had either a moderate (70.6%) or low degree (27.5%) of stress. There was a tendency toward higher stress ratings by female students, and this was statistically significant (p=0.046). Statistically

significant difference in degree of stress was also found between four study programmes. Students of medicine reported moderate and high degree of stress more frequently as compared to dentistry, speech therapy and nursing students (p=0.035). No significant difference was detected in the perceived stress degree among different years of study (p=0.313) (Table 1).

The students with moderate and high perceived stress degree reported a significantly lower quality of life assessed by EQ-5D (p<0.001). However, statistical difference between the groups with low, moderate, and high degree of perceived stress was not found in general self-assessment of HRQoL, as measured with EQ-5D VAS (p=0.161) (Table 2).

We compared the frequency of depression symptoms in students with different perceived stress degrees. Only 16 (3.7%) students scored positive for the presence of depression (mild), whereby the frequency of symptoms increased with the increase of the perceived stress degree (p=0.019) (Table 2). Females reported depression more frequently compared with their male counterparts (p=0.042).

The majority of students reported either mild (50%) or moderate (38%) levels of trait anxiety. Similarly to depression symptoms, there was an apparent stepladder appearance in distribution of trait anxiety levels according to perceived stress degree (p<0.001) (Table 2).

The state scale was used to assess how students anticipate their feelings in a variety of hypothetical situations. Students with higher levels of stress scored higher in the Stale Anxiety Scale than the students with low stress levels (p<0.001) (Table 2). Unlike trait anxiety, none of the students reported state anxiety level as severe.

A weak, statistically significant correlation (r=0.245, p<0.001) was found between state and trait anxiety. Greater elevation of state anxiety was detected in moderate and severe trait-anxious students.

Table 1. Degree of perceived stress assessed by 14-item Perceived Stress Scale, depending on different characteristics of examined students.

Variable	Perceived stress degree			P-value
	Low n (%)	Moderate n (%)	High n (%)	
Gender				
Male	46 (39.3)	84 (28.8)	1 (14.3)	0.046
Female	71 (60.7)	218 (71.2)	6 (85.7)	
Study program				
Medicine	29 (27.8)	114 (37.7)	4 (51.1)	0.035
Dentistry	46 (39.3)	73 (24.2)	2 (28.6)	
Speech therapy	23 (19.7)	68 (22.5)	1(14.3)	
Nursing	19 (16.2)	47 (15.6)	0	
Year of study				
Y1	41 (35.0)	120 (39.7)	1 (14.3)	0.313
Y2	24 (20.5)	78 (25.8)	3 (42.9)	
Y3	21 (17.9)	39 (12.9)	0	
Y4	11 (9.4)	21 (7.0)	0	
Y5	10 (8.5)	23 (7.6)	2 (28.6)	
Y6	10 (8.5)	21 (7.0)	1(14.3)	
Place of birth				
Urban	91 (77.8)	226 (74.8)	6 (85.7)	0.892
Rural	26 (22.2)	75 (24.8)	1 (14.1)	
Financial status				
Good	107 (91.5)	258 (85.4)	5 (71.4)	0.125
Poor	10 (8.5)	44 (14.6)	2 (28.6)	
Social support				
Good	116 (99.1)	292 (96.7)	6 (85.7)	0.071
Poor	1(0.9)	10 (3.3)	1 (14.3)	

Table 2. Perceived stress degree of examined students depending on quality of life, depression and anxiety symptoms.

Variable	Perceived stress degree			P-value
	Low n (%)	Moderate n (%)	High n (%)	
EQ-5D				
no problem	99 (34.3)	190 (44.6)	3 (0.7)	0.001
light difficulties	14(3.3)	59 (13.8)	3 (0.7)	
moderate difficulties	2 (0.5)	25 (5.9)	0	
severe difficulties	2 (0.5)	15 (3.5)	0	
extreme difficulties	0	13 (3)	5 (1.1)	
EQ-5D VAS				
0-40	2 (0.5)	8 (1.9)	0	0.161
41-70	6 (1.4)	38 (8.9)	0	
71-100	109 (25.6)	256 (60.1)	7(1.6)	
Depression				
no problem	117 (20.5)	287 (67.4)	6 (1.4)	0.019
mild	0	15 (3.5)	1 (0.2)	
Trait anxiety				
no problem	10 (2.3)	1 (0.2)	0	0.001
mild	97 (22.8)	116 (27.2)	0	
moderate	10(2.3)	149 (35)	3 (0.7)	
severe	0	36 (8.5)	4 (0.9)	
State anxiety				
no problem	117(27.5)	290 (68.1)	5(1.2)	0.001
mild	0	12 (1.8)	1(0.2)	
moderate	0	0	1(0.2)	

The multivariate linear regression analysis was used to find independent factors associated with the following outcome variables: perceived stress score, self-reported depression score, self-reported anxiety score, and HRQoL score. The results of the analysis presented in Tables 3 and 4 shows that the sociodemographic factors were not associated with any of analysed variables ($p>0.05$).

The significant independent factors associated with perceived stress were trait anxiety (OR, 0.339; CI 95%, 0.276-0.403, $p<0.001$) and EQ-5D score (OR, 0.044; CI 95%, 0.033-0.085, $p=0.036$). The presence of anxiety was the only significant determinant of depression score (OR, 0.085; CI 95%, 0.054-0.115, $p<0.001$) (Table 3). EQ-5D score was associated with perceived stress degree (OR, 0.243; CI 95%, 0.16-0.467, $p=0.036$) and high trait anxiety level (OR, 0.220; CI 95%, 0.053-0.386, $p=0.010$). Poor general health assessment was a risk factor for health-related quality of life (OR, -0.604; CI 95%, -0.833-0.374, $p<0.001$).

Table 3. Factors associated with perceived stress, depression, and HRQoL score (Multivariate linear regression analysis).

Factor	Perceived stress score*		Depression+		Health-related quality of life°	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P-value
Gender	0.076 (-0.012-0.165)	0.091	0.033 (-0.007-0.072)	0.102	-0.150 (-0.035-0.059)	0.160
Age	0.019 (-0.098-0.192)	0.524	0.05 (-0.10-0.21)	0.515	-0.315 (-0.654-0.025)	0.069
Study program	0.019 (-0.021-0.59)	0.352	-0.002 (-0.20-0.015)	0.803	-0.014 (-0.108-0.079)	0.764
Study year	-0.017 (-0.065-0.032)	0.507	-0003 (-0.024-0.019)	0.803	0.042 (-0.073-0.157)	0.475
Place of birth	0.002 (-0.36-0.40)	0.920	-0.004 (0.092-0.021)	0.617	0.023 (-0.67-0.112)	0.618
Financial status	0.012 (-0.116-0.139)	0.858	-0.035 (-0.21-0.12)	0.215	0.226 (-0.075-0.525)	0.139
Social support	0.054 (-0.201-0.309)	0.678	-0.023 (-0.089-0.136)	0.686	0.067 (-0.533-0.668)	0.826
Perceived stress	-		-0.015 (-0.058-0.027)	0.481	0.243 (0.16-0.467)	**0.036**
Depression	-0.078 (-0.297-0.140)	0.481	-	-	0.218 (-0.297-0.734)	0.405
Trait anxiety	0.339 (0.276-0.403)	**0.000**	0.85 (0.054-0.115	**0.000**	0.220 (0.053-0.386)	**.010**
EQ-5D score	0.044 (0.033-0.085)	**0.036**	0.008 (-0.010-0.026)	0.405	-	-
EQ-5D VAS score	0.87 (-0.013-0.187)	0.089	-0.36 (-0.88-0.009)	0.115	-0.604 (-0.833-0.374)	**.000**

P-value <0.05 is considered significant and bolded.
*Wald Chi-square=71.546, p<0.001; based on n=393 observations; SE (0.242)
+Wald Chi-square=19.606, p<0.001; based on n=225 observations; SE (0.334)
° Wald Chi-square=128.627, p<0.001; based on n=426 observations; SE (0.135)

A high degree of perceived stress (OR, 0.624; CI 95%, 0.507-0.704, p<0.001), the presence of depression (OR, 0.800; CI 95%, 0.513-1.087, p<0.001), and low quality of life were predictors of the trait anxiety (OR, 0.073; CI 95%, 0.018-0.128, p=0.020). State anxiety was a strong risk factor for trait anxiety (OR, 0.046; CI 95%, -0.084-0.007, p<0.001).

Perceived stress degree had a significant impact on the state anxiety level (OR, 0.696; CI 95%, 0.579-0.812, p<0.001) among Bosnian health professions students. A significant association was found between trait and state anxiety score (OR,-0.351; CI95%, -0.546--0.157, p=0.002).

Table 4. Factors associated with trait and state anxiety score (Multivariate linear regression analysis).

Factor	Perceived stress score*		Depression+	
	OR (95% CI)	P	OR (95% CI)	P
Gender	0.56 (-0.065-0.176)	0.365	0.061(-0.032-0.003)	0.171
Age	-0.003 (-0.051-0.045)	0.822	-0.015 (-0.026-0.148)	0.103
Study program	0.039 (-0.093-0.015)	0.157	0.022 (-0.108-0.079)	0.256
Perceived stress	0.624 (0.507-0.740)	**0.000**	0.696 (0.579-0.812)	**0.000**
Depression	0.800 (0.513-1.087)	**0.000**	-0.081 (-0.298- 0.137)	0.466
Trait Anxiety	-	-	-0.351 (-0.546--0. 157)	**0.002**
State Anxiety	-0.046 (-0.084—0.007)	**0.020**	-	-
EQ-5D score	-0.240 (-0.375-0.106)	**0.000**	-0.018 (-0.009-0.046)	0.187

P-value <0.05 is considered significant and bolded.
+Wald Chi-square=392.26, p<0.001; SE (0.133)
*Wald Chi-square=256.76, p=0.006; SE (0.175)

4 DISCUSSION

The current study was conducted to assess the perceived stress and its association with anxiety, depression, and HRQoL in health professions students. As presented in Table 2, the majority of students perceived moderate stress (70.6%) and only 1.6% of them perceived a high degree of stress. This is consistent with the results of other studies demonstrating that university students around the globe are exposed to high levels of stress (38, 39). The reported prevalence of perceived stress among health professions students ranged from 31.2% in the United Kingdom (12) to 83.9% in Australia (39). This difference in the prevalence between the countries is considered to be the result of culturally different perception of stress or stressful event, but also of environmental factors, such as economic burden of studying, very high tuition fees, lack of family support, and higher or lower 'readiness' to report the stress or any other complaint (7).

Perceived stress was significantly associated with anxiety levels in the current study (Table 3 and 4), and was an independent determinant of both, state and trait anxiety. This is in line with the study of Bunevicius et al., showing independent association of anxiety symptoms with higher vulnerability to stress and lower level of emotional stability in medical students (40). High, significant correlation between perceived stress and anxiety level was also found in the study of Heinen at al., conducted on the sample of 385 first-year medical students (19), as well as in the studies carried out among dentistry (41) and nursing students (42). High trait-anxiety could have led to greater sensitivity to stress because of students' attention being aimed toward threats to self-worth and self-esteem (43), while negative relationship between state and trait anxiety might have exacerbated the encumbrance of manifest anxiety (32). The results of the aforementioned research emphasise that counselling focusing on anxiety during health profession education might be a possible option for stress reduction. The autogenous training and progressive muscle relaxation showed to be effective in reducing trait and state anxiety levels in medical students (44).

Although ANOVA analysis showed that the frequency of depression symptoms increased with the increase of stress (Table 2), the association between self-rated depression and perceived stress was not found, as presented in Table 3. This is contrary to several other studies reporting very strong associations between these two outcome variables (10, 26, 45). However, merely 3.7 % of students examined here fulfilled the criteria for self-rated depression, in all cases it was rated as mild, which could explain why depression was not found to be the determinant of perceived stress.

A strong association was found between trait anxiety and depression score (Tables 3 and 4). Living in a constant state of anxiety can make the individual feel there is no hope for ever getting better and that life is not good, which creates a direct path to depression. Having depression during undergraduate studies can cause academic, psychosocial, physical, or academic related hindrances, as it is has been previously detected (46).

Regarding the role of quality of life, its relatedness to perceived stress, trait anxiety, and self-assessment of general health was demonstrated in the current study (Table 3). A portrait of stress levels and HRQoL has been provided in previous analyses, accentuating that higher vulnerability to stress in health professions students may be a predisposing risk factor for mental distress and poor physical heath (47). Our findings further support the necessity of providing predisposed students with programmes to alleviate their stress and boost their overall health (47).

ANOVA analysis showed higher levels of perceived stress in females than in males, and in medical students than in those of other programmes (Table 2). However, in a multivariate regression analysis neither gender nor study programme appeared as significant independent factors associated with perceived stress (Table 3). No association between gender and perceived stress was also reported in studies from Norway (48) and Germany (49), but studies from Sweden (14), Ethiopia (45), and Middle East (50) reported gender difference regarding stress perception. Different results in the studies may be subjected to a different degree of female discrimination, community pressure, and cultural habits.

The perceived stress in students of medicine did not differ from that in the students of dentistry, nursing, and speech language therapy. Controversial results were published on the relationship between health professions programmes of study and students' stress perception. Some found higher incidence of stress in medical students than in dental and nursing students (51), but the other reported lower stress levels in medical than in dental students (52, 53). These inconsistent findings indicate that in addition to the study programme, there are other independent factors that might increase one's proneness to stress.

4.1 Limitations of the Study

The current study has several limitations. The results may not be generalised, as the study was conducted in health professions students of one faculty of medicine, the socio-demographic structure of which was not necessarily the same as at the other faculties in Bosnia and Herzegovina. This was a cross-sectional study that assessed perceived stress degree of students at one point

in time. The association between stress and academic performance was not analysed, although it would be interesting and important. Future research should be directed towards identifying personal and occupational stressors that contribute the most to the stress, as well as possible intervention to help students cope with them better. Longitudinal study through study years could show changes in perceived stress over time. Studies to identify factors that may mediate the relationship between perceived stress and depression in health professions students have to be conducted.

4.2 Study Implications

Decision-makers in academic programmes should focus more on students' well-being and provision of counselling services, which could help the students to effectively cope with, and manage the stress. These programmes will provide the opportunity to identify the students who are at greatest risk for psychological maladjustment during undergraduate training, and protect them against negative effects of stress, such as development of anxiety or depression.

Less stressful learning environment should be created, and help-seeking behaviour promoted. Starting a high-impact mentoring programme could potentially improve social support and affect perceived stress levels. Medical education should encourage resilience against stress, by increasing and maintaining empathy throughout whole undergraduate studies (54, 55).

5 CONCLUSION

Higher levels of perceived stress predispose students for anxiety and lower HRQoL. Although medical students reported higher levels of stress compared to the students of dentistry, nursing, and speech language therapy, the study programme was not a significant determinant of perceived stress score. The screening of stress among health professions students should become a regular practice, and those students experiencing high levels of stress should be undergoing screening for anxiety and depression. Interconnection of stress, trait and state anxiety, and HRQoL merits further investigation and development of appropriate interventions.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The research protocol was approved for each survey by the Ethical Committee of the Faculty of Medicine Foča. All personal data were anonymised.

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VALIDATION OF THE SLOVENIAN VERSION OF MULTIPLE SCLEROSIS QUALITY OF LIFE (MSQOL-54) INSTRUMENT

POTRDITEV SLOVENSKE VERZIJE VPRAŠALNIKA O KAKOVOSTI ŽIVLJENJA PRI MULTIPLI SKLEROZI (MSQOL-54)

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ABSTRACT

Purpose. To cross-culturally adapt and validate Multiple Sclerosis Quality of Life-54 (MSQOL-54) instrument.

Methods. The study which enrolled 134 Slovenian multiple sclerosis (MS) patients was conducted from March to December 2013. The internal consistency of the MSQOL-54 instrument was evaluated by Cronbach's alpha coefficient (α), and its dimensionality assessed by the principal component analysis (PCA).

Results. The whole instrument had high internal consistency (α=0.88), as well as the majority of its twelve subscales (α=0.83-0.94). The results of the PCA showed two components with eigenvalue greater than 1, explaining 59.4% of the cumulative variance. Further results indicated good construct validity of the instrument with the physical health-related-quality-of-life subscales loading highly on the physical component, and mental health-related-quality-of-life subscales loading highly on the mental component.

Conclusion. The Slovenian version of the MSQOL-54 instrument proved to be an internally consistent and accurate tool, well accepted by the Slovenian MS patients. The adequate psychometric properties warrant the scientifically sound version of the MSQOL-54 instrument, which is from now on at disposal to all health professionals dealing with MS patients in Slovenia.

Keywords:
multiple sclerosis, MSQOL-54 instrument, reliability, validity, Slovenia

IZVLEČEK

***Namen**. Medkulturno prilagoditi in potrditi Vprašalnik o kakovosti življenja pri multipli sklerozi (MSQOL-54).*

***Metode**. Študija, ki je vključevala 134 slovenskih bolnikov z multiplo sklerozo (MS), je potekala od marca do decembra 2013. Notranja skladnost prevedenega vprašalnika je bila ocenjena s Cronbachovim koeficientom alfa (α), njegova dimenzionalnost pa z analizo glavnih komponent (AGK).*

***Rezultati**. Prevedeni vprašalnik kot celota je imel visoko notranjo skladnost (α=0,88), prav tako tudi večina njegovih dvanajstih podlestvic (α=0,83-0,94). Rezultati AGK so pokazali na dve pomembni komponenti, s katerima je moč pojasniti 59,4% skupne variance. Rezultati so pokazali tudi dobro konstruktno veljavnost instrumenta, saj so se podlestvice, ki merijo telesno komponento z zdravjem povezane kvalitete življenja dobro skladale s telesno komponento, ugotovljeno v analizi, podlestvice, ki merijo duševno komponento z zdravjem povezane kvalitete življenja, pa dobro z duševno komponento, ugotovljeno v analizi.*

***Zaključek**. Slovenska različica MSQOL-54 se je izkazala za notranje skladno in natančno orodje, ki so ga slovenski bolniki z MS dobro sprejeli. Ustrezne psihometrične lastnosti kažejo na znanstveno zanesljivo različico instrumenta MSQOL- 54, ki je zdaj na razpolago vsem zdravstvenim delavcem, ki se v Sloveniji ukvarjajo z bolniki z MS.*

Ključne besede:
multipla skleroza, vprašalnik MSQOL-54, zanesljivost, veljavnost, Slovenija

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1 INTRODUCTION

Multiple sclerosis (MS) is a chronic neurological disease complexly deteriorating the health of the patients (1). According to the World Health Organisation MS is classified among major public health problems (2) and in Europe, it is considered the leading cause of non-traumatic disability in young adults (3). The effect of disability in daily living is reported to be greater in comparison to other chronic diseases (4-6).

The impact of MS on health has been determined mainly through the physical disability measures over the past years. The gold standard for assessing physical disability in clinical settings has been the Kurtzke's Expanded Disability Status Scale (EDSS) (7). However, health has not only the physical component, but is rather a state of complete physical, mental, and social well-being (8). Conventional physical disability scales omit mental and social health dimensions that substantially contribute to the patient's overall quality of life. Moreover, the difficulties which are perceived important by patients substantially differ from those ones which doctors assess based on physical disability measures (9). Health-related-quality-of-life (HRQoL) instruments are increasingly recognized as indispensable tools for clinicians, not only to systematically assess patients' self-perceived HRQoL, but also to tailor care and therapy programmes according to the patient's individual needs (10), which is a novel treatment approach in the increasingly important new field of medicine, i.e. a personalised medicine. Patient-reported outcomes are also known to improve a patient-doctor communication, because the patients receive a positive signal that the physicians are interested in an array of issues concerning their illness, which, in turn, makes them feel understood. In addition, the patients are empowered being able to participate in the decision-making process related to the personalized treatment approach (5).

There exist a wide range of instruments for measuring the HRQoL concept. The generic ones are applicable to different populations and allow comparisons among them, but they do not address specific areas of concern to specific population groups, e.g. MS patients. The instrument Multiple Sclerosis Quality of Life-54 (MSQOL-54) was the first disease-specific HRQoL instrument which included items covering specific MS symptoms and signs (11). This instrument captures the whole burden experienced by MS patients and provides a more complete picture of their health and well-being (1). The instrument was initially developed in the US in the English language, and ever since it has been adapted to, and validated in numerous other languages (12-20).

Information about the burden of MS in Slovenia is sparse. The existing data showed the prevalence of 83/100,000 in early 1990s (3), while the newest available data showed even higher prevalence (>100/100,000) (21), classifying Slovenia among countries with the highest prevalence worldwide. In addition, due to a long life-span, the disability burden of the Slovenian MS patients is even higher nowadays (22).

To our knowledge, the HRQoL construct was not assessed among Slovenian MS patients yet, and no translated, adapted, and psychometrically sound Slovenian version of MSQOL-54 exists. So far, only two generic instruments measuring HRQoL were translated into Slovenian language and psychometrically tested, i.e. the generic SF-36 instrument (23) and the EQ-5D instrument (24).

It is very important for clinical as well as for research purposes to know whether the psychometric instrument reliably and validly measures what it intends to measure in each specific population within a specific culture.

Therefore, the aim of the present study was to prepare a valid Slovenian translation of the MSQOL-54 instrument for measurement of HRQoL of Slovenian MS patients in a context of a salutogenic approach to this vulnerable population group. In this frame, the objectives of the study were a forward-backward translation and linguistic validation of MS-18 module as well as psychometric testing of the complete MSQOL-54 instrument.

2 METHODS

The present cross-sectional study, in which the methodological approach similar to other comparable studies was used (12,14-19,25,26), was a part of a larger research project on the impact of the sense of coherence on quality of life and self-rated health in MS patients in Slovenia. In this project, it was planned to measure the quality of life with the MSQOL-54 instrument. Before using it for this purpose, the instrument was required to be validated in the observed population.

2.1 Observed Population

Out of all consecutive 207 patients, scheduled for a regular follow-up at the Department of Neurology of the University Clinical Centre Maribor between March and December 2013, all those who met the inclusion criteria, being the diagnosis of MS according to McDonald's criteria (27) and age 18+ years, were invited to participate in the study. Exacerbation of MS in the period of 30 days prior the scheduled neurological examination (a current, on-going active phase of the disease) and co-existing other chronic diseases were considered as exclusion criteria (12, 16-19).

2.2 Translation and Linguistic Validation

2.2.1 Description of MSQOL-54 Instrument

The MSQOL-54 is an instrument, developed by the UCLA Department of Neurology (28), created by adding 18 items relevant to MS patients, i.e. MS-18 module, to the generic HRQoL instrument, i.e. the Short-Form-36 Health Survey (SF-36) (11, 29). The instrument has two main dimensions and several sub-dimensions (28); consequently, it is comprised of 12 subscales (physical health, role limitations due to physical problems, role limitations due to emotional problems, pain, emotional well-being, energy, health perceptions, social function, cognitive function, health distress, sexual function, the overall quality of life) and two single-item measures (change in health, satisfaction with sexual function) (28). These subscales are summarized into the two summary composite scores: the physical health composite score (PHC) (comprised of physical health, role limitations due to physical problems, pain, energy, health perceptions, social function, health distress and sexual function subscales) and the mental health composite score (MHC) (comprised of role limitations due to emotional problems, emotional well-being, cognitive function, health distress and the overall quality of life subscales) (28).

2.1.2 The Translation into the Slovenian Language

After obtaining the written permission of the author of the original MS-18 module, two well-qualified translators performed the translation of this module into Slovenian. The translators were certified, bilingual, bicultural, with distinct professional backgrounds, the first being a professional literary translator and the second one a professional medical translator. A single preliminary draft was synthesized from the two forward translations by a group consisting of the members of the narrower research team (all of them being physicians), nurses, specialized in care for MS patients, MS patients, and translators. Afterwards, a certified translator, native in English, who had never seen the original English instrument, translated the preliminary version back into English.

Finally, the aforementioned group compared the original and the back-translated version to identify semantic and conceptual discrepancies. Subsequently, the differences between the original and the translated versions were addressed in a group discussion by using the method of voting and ranking. The solutions with the highest total ranking were accepted in the final version. This stage led to the Slovenian version of MS-18 module which was linguistically most equivalent to the original. The Slovenian version of MSQOL-54 was created by adding the Slovenian SF-36 questionnaire (23) to the linguistically adapted Slovenian MS-18 module.

2.3 Administration of the Instrument and Other Data Acquisition

In the presence of the neurology resident and two MS nurses, each participant completed the Slovenian version of MSQOL-54 instrument. Assistance in reading, writing, and explanation was provided, if required.

Along with the MSQOL-54 instrument the socio-demographic data (gender: male, female; age; education: primary, secondary, college or higher; employment status: employed, unemployed, retired; marital status: single, married/cohabiting; area of living: rural, urban) were also collected. The clinical data, i.e. the MS duration in years, the disease course (primary progressive, secondary progressive, relapsing-remitting), clinical worsening of MS in the past year prior the neurological examination, excluding the period of 30 days prior the examination (a relapse of relapsing-remitting type of MS or an increase of the EDSS score by 1 point in progressive type of MS; yes, no), the immunomodulatory therapy (yes, no), and the EDSS score were extracted from the patients' medical records.

2.4 Acceptability of the Instrument

Acceptability was assessed by estimating the mean time-to-complete the questionnaire (recommended administration time 11-18 min (30)), the percentage of missing data, and the assistance required by the patients in terms of reading, writing, or explanation of the questionnaire's items.

2.5 Psychometric Validation

The Expectation-Maximization technique was used to replace the missing values, and the descriptive statistics to describe the study participants' characteristics.

In order to assess the instrument's reliability, the internal consistency was assessed by calculating the Cronbach's alpha coefficient (α), ranging from 0-1, the latter meaning perfect internal consistency. The instrument was considered as internally consistent, if $\alpha \geq 0.70$ (31).

In order to assess the construct validity, the dimensionality of the instrument was assessed by conducting the principal component analysis (PCA) on 12 instrument subscales with varimax orthogonal rotation (32). A preliminary analysis concerning the data screening, assumption testing and sampling adequacy was performed using the Kaiser-Meyer-Olkin (KMO) statistic with appropriate values >0.5 and the Bartlett's sphericity test with $p \leq 0.05$. The components with associated eigenvalues >1 were retained in the analysis. Component loadings were used to indicate the inclusion of variables into the separate components.

SPSS statistical software version 19.0 was used as statistical tool (SPSS Inc., Chicago, IL, USA).

3 RESULTS

3.1 Study Group Characteristics

Out of 207 MS patients initially considered for inclusion, 134 were finally enrolled in the study, while 73 did not meet inclusion criteria: 55 (75.3%) had comorbidity, 2 (2.7%) had a recent exacerbation of MS, and 16 (21.9%) refused to participate in the study.

Among participants, there were 42 males (31.3%) and 92 (68.7%) females. The mean age was 43.2±11.1 years (age range: 21-72 years). All other participants' characteristics are presented in the Table 1.

Table 1. Characteristics of the multiple sclerosis (MS) patients for validation of the Slovenian version of Multiple Sclerosis Quality of Life-54 questionnaire (n=134).

Characteristic	Category	No. (%)/ Median; Min-Max; Q1-Q3
Education	Primary	16 (11.9)
	Secondary	94 (70.1)
	College or higher	24 (17.9)
Employment status	Employed	63 (47.0)
	Unemployed	18 (13.4)
	Retired	53 (39.6)
Marital status	Single	44 (32.8)
	Married/ cohabiting	90 (67.2)
Area of living	Rural	80 (59.7)
	Urban	54 (40.3)
Disease duration (years)		8; 0-33; 4-12.25
Disease course	Primary progressive	6 (4.5)
	Secondary progressive	23 (17.2)
	Relapsing-remitting	105 (78.4)
Clinical worsening of the disease*	Yes	51 (38.1)
	No	83 (61.9)
Immunomodulatory therapy	Yes	92 (68.7)
	No	42 (31.3)
EDSS		3.0; 0.0-8.0; 1.625-4.5

LEGEND: Q1 – the first quartile; Q3 - the third quartile; *- clinical worsening of the disease in the past year prior the neurological examination, excluding the period of 30 days prior the examination (a relapse of relapsing-remitting type of MS or an increase of the EDSS score by 1 point in progressive type of MS; EDSS - Expanded Disability Status Scale score

3.2 Acceptability Analysis Results

The average time to complete the questionnaire was 15.9±8.9 minutes. Most of the participating patients (94.8%) did not require additional explanation of the translated items. Thirty-two patients (23.9%) needed assistance in reading and writing due to the visual or upper extremity impairments. The percentage of missing data was generally low, ranging from 0.8% to 3.7% (Table 2).

Table 2. The total number and percentage of missing answers within a subscale/single item measure in the Slovenian version of Multiple Sclerosis Quality of Life-54 questionnaire validation study.

Subscale/Item	N of items	Total N of answers	N of missing answers	% of missing answers
Subscales				
Physical health	10	1323	17	1.3
Role limitations due to physical problems	4	525	11	2.1
Role limitations due to emotional problems	3	396	6	1.5
Pain	3	397	5	1.2
Emotional well-being	5	655	15	2.2
Energy	5	660	10	1.5
Health perceptions	5	664	6	0.9
Social function	3	395	7	1.7
Cognitive function	4	531	5	0.9
Health distress	4	532	4	0.8
Sexual function	4	520	16	3.0
Overall quality of life	2	264	4	1.5
Single-item measures				
Change in health	1	133	1	0.8
Satisfaction with sexual function	1	129	5	3.7

3.3 Psychometric Validation Results

3.3.1 Reliability

The whole instrument had a high internal consistency (α=0.88), as well as the majority of the separate subscales. Exceptions were the health perception, and the social function subscales (Table 3).

3.3.2 Validity

The KMO statistic verified a sampling adequacy for the analysis (KMO=0.88), and the Bartlett's test indicated sufficiently large correlations between the subscales for the PCA ($p<0.001$). The results of the PCA showed that only the first two components had the eigenvalues exceeding 1, accounting for 59.4% of the total variance (Table 4). Consequently, only these two components were retained in the analysis. In Table 5, the component loadings after rotation are shown. The emotional well-being, the cognitive function, the health distress, and the overall quality of life subscales all related to the mental dimension of MSQOL-54 and loaded highly on component 1, suggesting this component is, in fact, the mental component. The physical health, the role limitations due to physical problems, the pain, the health perceptions, the social, and the sexual function subscales all related to the physical dimension of MSQOL-54 and loaded highly on component 2, suggesting this component as the physical component. The energy subscale, originally the subcomponent in the physical health component, also showed a high loading on mental health. The role limitations due to emotional problems subscale was the only subscale loading about equally on both components.

Table 3. Statistical description and the Cronbach's Alpha (α) for the Slovenian version of Multiple Sclerosis Quality of Life-54 questionnaire subscales/single item measures (n=134).

Subscale/Item	N of items	Mean	SD	α
Subscales				
Physical health	10	55.7	29.6	0.94
Role limitations due to physical problems	4	33.1	41.0	0.90
Role limitations due to emotional problems	3	62.7	41.3	0.83
Pain	3	65.9	24.0	0.89
Emotional well-being	5	74.4	15.9	0.84
Energy	5	55.2	19.2	0.84
Health perceptions	5	44.6	14.8	0.58
Social function	3	72.8	19.3	0.68
Cognitive function	4	71.4	23.2	0.91
Health distress	4	72.0	19.9	0.85
Sexual function	4	71.4	28.2	0.90
Overall quality of life	2	67.8	15.9	0.86
Single-item measures				
Change in health*	1	45.3	22.6	
Satisfaction with sexual function*	1	61.4	25.7	

LEGEND: SD - standard deviation; *- α was not computed because the scale is based on a single item.

Table 4. Component loadings after rotation in the Slovenian version of Multiple Sclerosis Quality of Life-54 questionnaire validation study (n=134).

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of variance	Cum. %	Total	% of variance	Cum. %	Total	% of variance	Cum. %
1	5.906	49.2	49.2	5.906	49.2	49.2	3.659	30.5	30.5
2	1.219	10.2	59.4	1.219	10.2	59.4	3.466	28.9	59.4
3	0.938	7.8	67.2						
4	0.765	6.4	73.6						
5	0.625	5.2	78.8						
6	0.564	4.7	83.5						
7	0.479	4.0	87.5						
8	0.423	3.5	91.0						
9	0.349	2.9	93.9						
10	0.277	2.3	96.2						
11	0.257	2.1	98.4						
12	0.198	1.6	100.0						

Table 5. Component loadings after rotation in the Slovenian version of Multiple Sclerosis Quality of Life-54 questionnaire validation study (n=134).

Subscale	Rotated factor loadings	
	Component 1 Mental component	Component 2 Physical component
Physical health	0.129	0.854
Role limitations due to physical problems	0.184	0.792
Role limitations due to emotional problems	0.472	0.475
Pain	0.275	0.570
Emotional well-being	0.874	0.104
Energy	0.750	0.407
Health perceptions	0.415	0.536
Social function	0.474	0.654
Cognitive function	0.754	0.174
Health distress	0.698	0.320
Sexual function	0.202	0.590
Overall quality of life	0.701	0.432

4 DISCUSSION

The results of this study showed that the Slovenian version of the MSQOL-54 instrument successfully passed the evaluation for cultural equivalence as well as fulfilled the required psychometric criteria. The instrument was well accepted by the Slovenian MS patients, with the majority of them stating there were no items difficult to interpret. Almost all the patients completed the questionnaire within the recommended period, indicating that it was easy to understand and manageable to accomplish. The greater portion of participants could fill in the questionnaire without any intervention by the research team, which is in line with the preferred self-administered mode. Nevertheless, in one sixth of the patients, the MSQOL-54 instrument was administered as an interview due to the visual or upper extremity impairments. Therefore, the acceptability is likely to improve if the questionnaire is administered in settings where help is accessible. The percentage of the missing answers was low, except for the items referring to the sexual function and satisfaction with the sexual function. A pattern of a higher percentage of the missing answers in the sexual function subscale was detected in the original US study as well as in other similar studies dealing with MSQOL-54 validation (11, 12, 15, 18, 19). This could be explained by a traditional perception of sexuality as a taboo in many cultures.

The individual subscales and the complete instrument had a high internal consistency, indicating an internally consistent instrument. However, in the health perception and the social function subscales, it was below the recommended cut-off point. The aforementioned subscales also had the lowest coefficients in the original US study and in several other published MSQOL-54 validation studies (11, 14, 17-19). The health perception subscale contains items that cover quite broad aspects of health self-evaluation, and this might explain the relative lack of consistency. Furthermore, the social function subscale contains only three items, therefore its reduced reliability could be attributed to the low number of items. In this study, two underlying dimensions of the instrument's construct have been confirmed. The two extracted components by the PCA represented the physical and the mental HRQoL dimensions. The analysis also revealed that subscales, which in the original US study (11) are related to the physical HRQoL dimension and unrelated to mental HRQoL dimension, loaded highly on the physical component. Likewise, the subscales originally intended to pertain in the mental dimension, made up the mental component in our study, too. Therefore, the Slovenian MSQOL-54 instrument has good discriminant validity. An exception from the aforementioned was the energy subscale, which was originally stapled as the physical dimension subscale, while in our study, it appeared to fit more into the mental component. Similarly, to our finding, two other studies evidenced that the energy subscale measured by MSQOL-54 was primarily an emotional component (14, 17). Moreover, in our study, the role limitations due to emotional problems subscale had equal loadings on both components. Likewise, in the Israeli validation study (14), this subscale emerged together with the role limitations due to physical problems subscale as a separate dimension, suggesting that patients view role limitations as unitary, tending to overlook the source of the limitations.

There are some limitations of this study. Firstly, a relatively small number of participants were included in the study; however, the number was still sufficient to permit fair conclusions. Moreover, one could argue that item response theory statistics has not been used in the present study since this methodology is increasingly used for the purpose of psychometric validation of instruments. However, most of the studies reporting the validation of the translated versions of the MSQOL-54 instrument in the past used the classical methodology. In order to make our results comparable to the results of other similar studies, a classic methodology was used in our study as well. Furthermore, one could argue that no method of measurement of the stability of the instrument over time, e.g. the test-retest method, was used in the present study. However, the reliability of

the measurement can be evaluated using measurement stability methods and/or measurement equivalence methods. The later were developed in the social science research for the situations in which it is not possible to perform repeated measurements, because the measured phenomenon changes or could change over time (33). As we assumed that the phenomenon measured in our study could change over time, the measurement at the same time was used and the internal consistency method was used as an appropriate method (33). Finally, only the exploratory factor analysis was performed; however, the intention of the study was to explore if data collected by the translated version of the instrument fit the expected pattern.

Nonetheless, the study has also some important strengths. Firstly, the rigorously performed forward-backward translation process provided a good quality translation of the MSQOL-54 instrument to the Slovenian language, making it available to all Slovenian experts dealing with MS patients in clinical settings as well as for the research purposes. Secondly, this study provided the information on the psychometric properties when used in Slovenian MS patients. According to the results of this study, the Slovenian MSQOL-54 instrument is valid and reliable, and the users can trust it, and use it as a valid and reliable measurement tool. These benefits give the opportunity for treating MS patients in Slovenia in accordance to personalised medicine approach. Finally, the study could be another step in the implementation of a comprehensive approach to managing major public health problems in Slovenia.

There are still many challenges left in researching both the properties of the MSQOL-54 instrument and the content of the instrument itself. With a focus on studying the properties of the Slovenian version of the instrument, further evaluation is needed. Our work can be continued by assessing the instrument's responsiveness, exploring the relations between the MSQOL-54 dimensions and another HRQoL instrument, as well as by performing the confirmatory factor analysis, while working on larger clinical data sets. With a wider focus, at the content level of the instrument, another challenge for researchers could be to combine the MS-18 module with another HRQoL instrument than SF-36, e.g. the EQ-5D (34).

5 CONCLUSION

The Slovenian version of the MSQOL-54 proved to be internally consistent and accurate tool, well accepted by the Slovenian MS patients. The adequate psychometric properties warrant the scientifically sound Slovenian version of the MSQOL-54 instrument, which is from now on at disposal to all health professionals dealing with MS patients in Slovenia.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

FUNDING

The study received no funding.

ETHICAL CONSIDERATIONS AND PERMISSIONS

The study was launched after receiving permissions to use MSQOL-54 and SF-36 instruments from their developers. It was approved by the Medical Ethics Committee of the Republic of Slovenia on 17 July 2012 (approval No. 24k/07/12).

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THE OUTCOMES OF PREGNANCY AND CHILDBIRTH IN ADOLESCENTS IN SLOVENIA

IZIDI NOSEČNOSTI IN PORODA PRI MLADOSTNICAH V SLOVENIJI

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ABSTRACT

Introduction. The objective of the study was to determine the course and outcomes of pregnancy and childbirth in adolescents compared to women aged 20-24 years in Slovenia.

Methods. In the retrospective study, the course of pregnancy and labour and the perinatal outcome of newborns in primiparous adolescents aged ≤19 years (study group) have been compared to the control group of primiparous women aged 20-24 years. The study group was further divided into a study subgroup of adolescents aged ≤17 years. Data were retrieved from the National Perinatal Information System in Slovenia for the period 2008-2012. Altogether, 13,663 women and their newborns were included.

Results. Adolescent pregnancy was associated with increased rates of unknown estimated date of delivery, preterm labour, low birth weight newborns, small for gestational age newborns and low gestational weight gain. Spontaneous labour was more common in adolescents, while emergency and elective Caesarean sections were less common than in women aged 20-24 years. In addition, pregnancy in adolescents aged ≤17 years was associated with increased rate of maternal anaemia and labour without complications. Higher rates of smoking, lower rates of parenting school attendance, lower rates of pregnancy check-ups and screening tests in pregnancy such as nuchal translucency in adolescents were found.

Conclusions. The results of the study show that adolescent pregnancy is related to higher health risks for pregnant adolescents and their newborns. In addition, adolescents are subject to poorer prenatal care comparing to older women.

Keywords:
teenagers, delivery, birth, labour, complications, newborn, birth weight, gestational weight gain

IZVLEČEK

***Uvod**. Namen dela je bil na nacionalni ravni analizirati podatke o poteku nosečnosti in poroda ter podatke o izidu za novorojenčka slovenskih mladostnic. Želeli smo ugotoviti pojavnost zapletov v nosečnosti, med porodom in pri novorojenčku ter značilnosti predporodnega varstva med slovenskimi prvesnicami, starimi do 19 let, v primerjavi s prvesnicami, starimi med 20 in 24 let.*

***Metode**. V retrospektivni raziskavi smo ugotavljali pojavnost zapletov v nosečnosti, med porodom ter izid za novorojenčka in značilnosti predporodnega varstva pri mladostnicah prvesnicah, starih do 19 let (študijska skupina), in mlajših od 17 let (študijska podskupina), ter ugotovitve primerjali s kontrolno skupino prvesnic, starih med 20 in 24 let. Podatke smo pridobili iz Nacionalnega perinatalnega informacijskega sistema Slovenije (NPIS) za obdobje od leta 2008 do leta 2012. Skupno je bilo v raziskavo vključenih 13.663 prvesnic in njihovih novorojenčkov.*

***Rezultati**. Nosečnost pri mladostnicah je povezana s povečanim tveganjem za nejasen predvideni datum poroda, prezgodnji porod, nizko porodno težo novorojenčka, novorojenčka, majhnega za gestacijsko starost in nizko pridobitvijo telesne teže med nosečnostjo. Spontan porod je pogostejši pri mladostnicah, medtem ko sta nujni in elektivni carski rez pri tej skupini manj pogosta kot pri ženskah, starih med 20 in 24 let. Nosečnost pri mladostnicah, mlajših od 17 let, je povezana s pogostejšo anemijo matere ter porodom brez zapletov. Mladostnice med nosečnostjo pogosteje kadijo, imajo med nosečnostjo manj pregledov in prenatalne diagnostike, kot je na primer nuhalna svetlina, redkeje tudi obiskujejo šolo za starše.*

***Zaključki**. Rezultati raziskave kažejo, da je nosečnost pri mladostnicah povezana z višjim tveganjem za zdravje nosečnice in novorojenčka. Mladostnice imajo tudi slabše predporodno varstvo kot starejše ženske.*

Ključne besede:
adolescentke, najstnice, porod, rojstvo, zapleti, novorojenčki, porodna teža, pridobitev telesne teže

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1 INTRODUCTION

Adolescence is a period of human growth and development between childhood and adulthood, from ages 10 to 19 years. Many adolescents face pressures to initiate sexual relationships at earlier age, putting themselves at high risk for consequences from sexually transmitted infections to unintended pregnancies (1). Early childbearing increases the risks for both mothers and their newborns, and can also have negative social and economic effects on girls, their families and communities (2). Therefore, the adolescent pregnancy is a public health problem.

The research on sexual behaviour of secondary-school students in Slovenia in 1996, showed that median age of first sexual intercourse was 18.5 years (3) and dropped to 17.0 years in 2004 (4), and 17.6 years in 2012 (5). In 2012, contraceptive methods used at last sexual intercourse by 3rd grade secondary-school students were condom (54.1%), the pill (27.1%), double method (4.2%), withdrawal (4.0%), other methods (3.5%) and no method (7.1%) (5).

In Slovenia, abortion rates in women of reproductive age (aged 15–49 years) have decreased from 25.9 in 1992, to 8.8 in 2012; in women aged 15–19 years, from 12.7 in 1992, to 5.8 in 2012; in women aged 20–24 years, from 33.5 in 1992, to 11.1 in 2012. In the same period, fertility rates in women aged 15–49 years have increased from 39.1 in 1992, to 46.2 in 2012; however, in women aged 15–19 years, fertility rates decreased from 13.9 in 1992, to 4.6 in 2012, and in women aged 20–24 years, from 98.2 in 1992, to 43.7 in 2012 (6, 7). Slovenia had one of the lowest ratios of all live births to mothers aged below 20 years, 1.01 % in 2012 (8).

The studies showed that adolescents' pregnancy and childbirth were related to increased health risk for adolescents and newborns. Girls who got pregnant at the age of 14 years or younger, and, to a lesser extent, at 15–17 years and 18–19 years, were at higher risk of complications during pregnancy (9). They were more likely to experience obstructed labour, fistula, premature birth, and gave birth to low birth weight newborns than older women (10). Moreover, medical risks of adolescent pregnancy could include higher rates of anaemia, pregnancy-induced hypertension, cephalopelvic disproportion, problems with progression of labour, and higher perinatal morbidity (11–14). On the other hand, some studies showed that adolescent mothers had lower risks of third trimester bleeding, gestational diabetes (15) and preeclampsia (16).

Aiming at getting new insights in characteristics of adolescent pregnancy in Slovenia, the objective of our study was to determine the course and outcomes of pregnancy and childbirth in primiparous adolescents compared to primiparous women aged 20–24 years.

2 MATERIAL AND METHODS

The study was done on the total population of observed population groups of primiparous women aged up to 24 years, and their newborns in Slovenia for the period 2008–2012. In the retrospective study, the incidence of complications during pregnancy and labour and the perinatal outcome in primiparous adolescents aged up to 19 years (study group) was compared to the control group of primiparous women aged 20–24 years.

In the study, 13,663 primiparous women aged up to 24 years who gave birth during 2008–2012 in Slovenia, and their newborns were included: 1,413 adolescents aged up to 19 years and their 1,423 newborns, and 12,112 women aged 20–24 years and their 12,240 newborns. The study group of primiparous adolescents (≤19 years) was further divided into a subgroup of adolescents aged up to 17 years (≤17 years, 318 women, 318 newborns). Data were retrieved from the National Perinatal Information System. In the study, the variables for the course of pregnancy, the course of labour, the status of the newborn and prenatal care were used. The majority of variables were observed outcomes, except for participants' age and gestational age at childbirth. Participants' age was an explanatory factor. In multivariate analyses, gestational age was the confounding factor. All dichotomous variables were coded accordingly (e.g. hypertension: 0=no, 1=yes).

Variables on body weight gain during pregnancy (i.e. gestational weight gain) in relation to body mass index (BMI) before pregnancy were used according to the Institute of Medicine guidelines (US) (17). The data were analysed by SPSS programme. Descriptive analysis, analysis of variance (ANOVA), x^2 test, correlation and multivariate analyses (multiple linear and multiple logistic regression) were applied where appropriate. Statistical significance was set at $p<0.05$.

3 RESULTS

3. 1 The Course of Pregnancy

Gestational diabetes and bleeding during pregnancy were less common in the study group of adolescents aged ≤19 years, while anaemia was more common only in the younger subgroup of adolescents aged ≤17 years. In addition, unknown estimated date of delivery, threatened preterm labour and preterm labour were more common in adolescents. It was more common for adolescents to have a low and appropriate gestational weight gain compared to women in the control group. No statistically significant differences regarding hypertension, intrauterine growth restriction (IUGR) and foetal anomalies were found (Table 1).

Table 1. Results of univariate analysis of the course of pregnancy group of observed outcomes between the study group (age ≤19 years) or the study subgroup (age ≤17 years) and the control group (age 20–24 years) of primiparous women, Slovenia, 2008–2012.

The course of pregnancy	Control group	Study group		Study subgroup	
	20–24 years (N=12,112)	≤19 years (N=1,413)		≤17 years (N=318)	
	n (%)	n (%)	P*	n (%)	P*
Hypertension	598 (4.9)	68 (4.8)	0.837	15 (4.7)	0.858
Anaemia	273 (2.3)	43 (3.0)	0.063	14 (4.4)	0.012
Gestational diabetes	265 (2.2)	10 (0.7)	<0.001	1 (0.3)	0.023
Unknown estimated date of delivery	55 (0.5)	27 (1.9)	<0.001	18 (5.7)	<0.001
Bleeding during pregnancy	616 (5.1)	41 (2.9)	<0.001	8 (2.5)	0.038
Intrauterine growth restriction (IUGR)	291 (2.4)	43 (3.0)	0.142	12 (3.8)	0.118
Foetal anomalies	33 (0.3)	4 (0.3)	0.942	2 (0.6)	0.236
Threatened preterm labour	473 (3.9)	82 (5.8)	0.001	21 (6.6)	0.015
Duration of pregnancy					
Birth at ≤31 weeks	124 (1.0)	28 (2.0)	0.001	7 (2.2)	0.017
Birth at 32–36 weeks	649 (5.4)	94 (6.7)		25 (7.9)	
Birth at ≥37 weeks	11338 (93.6)	1290 (91.4)		286 (89.9)	
Gestational weight gain in relation to BMI before pregnancy					
Appropriate gestational weight gain	3135 (26.0)	341 (24.2)	<0.001	81 (25.6)	<0.001
Low gestational weight gain	1986 (16.4)	357 (25.3)		104 (32.8)	
High gestational weight gain	6953 (57.6)	712 (50.5)		132 (41.6)	

Legend: * comparison to the control group – $\chi 2$ test

3.2 The Course of Labour

The onset of labour was more commonly spontaneous in adolescents; it was less common for adolescents to need either an administration of PGE2, artificial rupture of membranes or an elective Caesarean section. No differences were found regarding augmentation with oxytocin or regarding foetal position and breech presentations. It was less common for adolescents to have an incorrect descent of the presenting part, emergency Caesarean section and minor maternal injuries. Instrumental interventions were more frequent in adolescents. No statistically significant differences were found in delay of cervical dilatation, foetal distress, rates of labour dystocia, episiotomy, uterine cervix and severe maternal injuries and complications of the third stage of labour (Table 2).

Table 2. Results of univariate analysis of the course of labour group of observed outcomes between the study group (age ≤19 years) or the study subgroup (age ≤17 years) and the control group (age 20–24 years) of primiparous women, Slovenia, 2008–2012.

The course of labour	Control group	Study group		Study subgroup	
	20-24 years (N=12,112)	≤19 years (N=1,413)		≤17 years (N=318)	
	n (%)	n (%)	P*	n (%)	P*
Onset of labour					
Spontaneous	9197 (76.1)	1.152 (81.7)	<0.001	269 (84.6)	0.006
Administration of PGE2	1.451 (12.0)	139 (9.9)	<0.001	25 (7.9)	0.006
Artificial rupture of membranes	971 (8.0)	79 (5.6)	<0.001	16 (5.0)	0.006
Elective Caesarean section	465 (3.8)	40 (2.8)	<0.001	8 (2.5)	0.006
Augmentation with oxytocin	7751 (64.0)	875 (61.9)	0.126	188 (59.1)	0.074
Foetal position					
Occipito-anterior foetal position	10857 (88.7)	1270 (89.2)	0.927	280 (87.8)	0.614
Other foetal head positions	785 (7.4)	89 (6.3)	0.927	25 (7.8)	0.614
Breech presentations	567 (4.6)	61 (4.3)	0.927	14 (4.4)	0.614
Delay of cervical dilatation	252 (2.1)	15 (1.1)	0.09	1 (0.3)	0.028
Incorrect descent of the presenting part	754 (6.2)	67 (4.7)	0.027	16 (5)	0.383
Foetal distress	503 (4.2)	62 (4.4)	0.676	13 (4.1)	0.954
Labour dystocia	84 (0.7)	9 (0.6)	0.808	5 (1.6)	0.067
Instrumental intervention (vacuum, forceps)	556 (4.5)	62 (4.4)	0.001	18 (5.6)	0.040
Emergency Caesarean section	2006 (16.4)	180 (12.6)	0.001	36 (11.3)	0.040
Episiotomy	5432 (44.9)	482 (44.0)	0.872	155 (48.7)	0.169
Maternal injuries					
Minor injuries	2937 (24.2)	298 (21.1)	0.008	75 (23.6)	0.785
Uterine cervix injury	199 (1.6)	25 (1.8)	0.725	9 (2.8)	0.103
Severe injuries	46 (0.4)	4 (0.3)	0.571	0 (0.0)	0.271
Complications of the third stage of labour	420 (3.5)	48 (3.4)	0.891	17 (5.3)	0.073
Labour without complications	8902 (73.5)	1061 (75.1)	0.199	255 (80.2)	0.007

Legend: * comparison to the control group – $\chi 2$ test

Median duration of labour was 4 hours in all the study and control groups, while the interquartile range was 3–6 hours. Mann-Whitney test did not show any statistically significant difference among the groups.

3.3 The Status of the Newborn

Newborns of adolescents have had more commonly very low birth weight, and were more commonly small for gestational age (SGA). Furthermore, it was less common for newborns of adolescents to have an appropriate newborn's birth weight as well as excessive newborn's birth weight. There was no statistically significant difference in stillbirth or in Apgar score <7 at 1st minute (Table 3).

Table 3. Results of univariate analysis of the newborn status group of observed outcomes between the study group (age ≤19 years) or the study subgroup (age ≤17 years) and the control group (age 20–24 years) of primiparous women, Slovenia, 2008–2012.

Status of the newborn	Control group	Study group		Study subgroup	
	20-24 years (N=12,112)	≤19 years (N=1,413)		≤17 years (N=318)	
	n (%)	n (%)	P*	n (%)	P*
Stillbirth	62 (0.5)	7 (0.5)	0.941	0 (0.0)	0.202
Apgar score <7 at 1st minute	453 (3.7)	56 (3.9)	0.659	14 (4.4)	0.522
Apgar score <7 at 5th minute	156 (1.3)	33 (2.3)	0.001	7 (2.2)	0.152
Newborn's birth weight					
Very low newborn's birth weight <1500 g	133 (1.1)	25 (1.8)	<0.001	6 (1.9)	<0.001
Low newborn's birth weight 1500–2499 g	642 (5.2)	108 (7.6)		35 (11.0)	
Appropriate newborn's birth weight 2500–3999 g	10488 (85.7)	1193 (83.8)		265 (83.1)	
Excessive newborn's birth weight ≥4000 g	972 (7.9)	97 (6.8)		13 (4.1)	
Small for gestational age (SGA)	708 (5.8)	104 (7.3)	0.022	31 (9.7)	0.003

Legend: * comparison to the control group – $\chi 2$ test

Regarding the newborn's birth weight, the results of multivariate analysis showed that newborns of adolescents aged ≤17 years were on average 120 g lighter, and newborns of adolescent aged 18–19 years were 49 g lighter when adjusted for gestational age, compared to newborns of women aged 20–24 years (ß=-0.04 for age group ≤17 years, ß=-0.03 for age group 18–19 years; both were statistically significant, p<0.001).

Regarding SGA newborns, the results of multivariate analysis showed that full-term newborns were SGA in 10.1% if born to adolescents aged ≤17 years, and in 5.8% if born to adolescents aged 18–19 years, compared to 5.3% if born to women aged 20–24 years. Odds ratio for SGA was 1.8 (1.2–2.8) for adolescents aged ≤17years (p=0.002) and 1.1 (0.8–1.4) for adolescents aged 18–19 years (p=0.533).

3.4 Prenatal Care

Adolescents have had their first check-up at gynaecologist later in pregnancy; have had less check-ups at gynaecologist and less ultrasonography check-ups during pregnancy. Adolescents also less commonly attended parenting school, but more frequently smoked during pregnancy. It was less common for adolescents to get prenatal screening tests: nuchal translucency or cervix uteri measurement (Table 4).

4 DISCUSSION

4.1 Summary of the Most Important Results of the Study

Our study revealed that in Slovenia, anaemia in pregnancy was more common in adolescents aged ≤17 years than in women aged 20–24 years. Unknown estimated date of delivery was more common in adolescents, particularly in the adolescents aged ≤17 years. Preterm birth was also more common in adolescents. Adolescents' newborns had more commonly very low birth weight and low birth weight, they were lighter then newborns of women aged 20–24 years even after adjustment for gestational week. Additionally, full term newborns of adolescents aged ≤17 years were more frequently SGA, odds ratio for SGA was 1.8 (1.2–2.8), compared to full-term newborns of women aged 20–24 years. Last but not least, adolescents had poorer prenatal care. On the other hand, gestational diabetes was less common in adolescents, it was less common for adolescents to have a high gestational weight gain, there was more common spontaneous onset of labour, lower incidences of elective and emergency Caesarean sections in adolescents, and more commonly labour without complications in adolescents aged ≤17 years. There was no statistically significant difference in rates of hypertension and IUGR, nor in the presence of foetal anomalies.

4.2 Comparison and Contrast with the Findings of Similar Studies

Our findings on anaemia are congruent with other studies; anaemia is usually attributed to a lower socio-economic status and prenatal care in these women, as well as to a growing need for iron and other haemoglobin substrates (18, 19).Unknown estimated date of delivery could be attributable to the fact that a lot of adolescent women have their first check-up at gynaecologist later than older women, as it was obvious also in our study, and that it is common for adolescent women not to know the date of their last period, since their periods tend to be irregular (20). More frequent preterm birth in adolescents was found also in other studies (21). The mechanisms responsible for

Table 4. Results of univariate analysis of prenatal care group of observed outcomes between the study group (age ≤19 years) or the study subgroup (age ≤17 years) and the control group (age 20–24 years) of primiparous women, Slovenia, 2008–2012.

Prenatal care	Control group	Study group		Study subgroup	
	20–24 years (N=12,112)	≤19 years (N=1,413)		≤17 years (N=318)	
	n (%)	n (%)	P*	n (%)	P*
Week of the first check-up at gynaecologist			<0.001		<0.001
First check-up at gynaecologist <12 weeks of pregnancy	9966 (82.3)	888 (62.9)		1174 (54.7)	
First check-up at gynaecologist at 12–22 weeks of pregnancy	1800 (14.9)	370 (26.2)		95 (29.9)	
First check-up at gynaecologist ≥23 weeks of pregnancy	342 (2.8)	154 (10.9)		49 (15.4)	
No check-ups during pregnancy	50 (0.4)	30 (2.1)	<0.001	18 (5.7)	<0.001
Number of check-ups during pregnancy			<0.001		<0.001
1–7 check-ups during pregnancy	1.773 (14.6)	426 (30.1)		124 (39.0)	
8–12 check-ups during pregnancy	8305 (68.6)	810 (57.2)		154 (48.4)	
≥13 check-ups during pregnancy	1.983 (16.4)	147 (10.4)		22 (6.9)	
Number of ultrasonography check-ups			<0.001		<0.001
0–1 ultrasonography check-up	333 (2.8)	122 (8.6)		42 (13.2)	
2 ultrasonography check-ups	1660 (13.7)	284 (20.1)		78 (24.5)	
≥3 ultrasonography check-ups	10116 (83.5)	1006 (71.2)		198 (62.3)	
Parenting school attendance	8431 (69.6)	543 (38.5)	<0.001	68 (21.4)	<0.001
Smoking during pregnancy	2213 (18.3)	457 (32.4)	<0.001	121 (38.1)	<0.001
Nuchal translucency	8007 (66.1)	455 (32.0)	<0.001	45 (14.1)	<0.001
Cervix uteri measurement	937 (7.7)	61 (4.3)	<0.001	10 (3.1)	<0.002

Legend: * comparison to the control group – $\chi 2$ test

preterm birth are still unclear: the immaturity of cervical blood supply in young mothers stimulates prostaglandin production that could lead to a preterm birth (22).

More common spontaneous onset of labour in adolescents was observed also by other studies (16, 21). Some researches attributed a lower incidence of Caesarean sections to a lower newborns' birth weight and size of newborns of adolescents (21). There was no difference in foetal positions, breech presentations or in delay of cervical dilatation, which contrasts with studies founding breech presentations to be more common in adolescents (23). Maternal injuries were more common in adolescents, mostly due to higher rates of minor injuries. The study from Sweden, however, showed a significantly lower incidence of perineal rupture in adolescents (24).

We found no statistically significant difference in stillbirth or in Apgar score <7 at 1st minute. Apgar score <7 at 5th minute was more common in newborns of adolescents, compared to women aged 20–24 years. Some studies have found similarly lower Apgar scores in adolescents' newborns (25), while others have not (16). More commonly, very low birth weight and low birth weight in adolescents' newborns was found in many other studies (10, 11, 26), as well as SGA newborns of adolescents (15), but others found no difference regarding SGA newborns, when comparing adolescents to older women (23). It is interesting that we observed a higher incidence of SGA newborns and preterm births in adolescents, yet we did not observe any statistically significant difference regarding IUGR. This could be attributable to adolescents' late first check-up and poorer follow-up regarding growth restriction, due to a lower number of check-ups in adolescents overall. Not knowing the date of their last period and, consequently, unknown estimated date of delivery also attributes to a higher risk for missed IUGR diagnosis.

In general, adolescent women had their first check-up at the gynaecologist later than older women and a lower rate of regular check-ups and ultrasonography check-ups during pregnancy. A lower number of pregnancy check-ups could be due to the fact that adolescents make a later first check-up at the gynaecologist than older women, have higher incidence of preterm births, and that their check-ups are most frequent towards the end of pregnancy. More than two thirds of women aged 20–24 years and only one third of adolescents attended parenting school. A similar study has shown that adolescents in Slovenia have a poorer psychological readiness for pregnancy, lower education, and often live in rural areas and have poorer prenatal care

compared to older women. All of this attributes to a lower percentage of parenting school attendance (27). A higher prevalence of smoking during pregnancy in adolescents is congruent with other studies (28). Smoking has been recognised as an important risk factors for having SGA newborns (29) and has also been linked to a higher incidence of low birth weight newborns (30). We observed a much higher incidence in nuchal translucency in women aged 20–24 years than in adolescents. This could be due to a later first check-up in adolescents and, therefore, a missed time frame for nuchal translucency. Also, cervix uteri measurement was more common in women aged 20–24 years than in adolescents, which we could not explain with the current data.

Adolescents were more frequently underweight before pregnancy than older women. Moreover, the incidence of a low gestational weight gain was higher in adolescents. Studies have shown that adolescents with gestational weight gain under the recommendations, however, had decreased odds of having an LGA newborn and increased odds of having an SGA newborn (31). Moreover, they had increased odds of preterm birth and infant death (32). A lower gestational weight gain in adolescents could be attributable to the fact that many adolescents exhibit long bone growth during pregnancy and pelvic immaturity. This growth may lead to competition between mother and foetus for nutrients, suggesting that adolescents may require greater gestational weight gain than adult women to optimize outcomes in pregnancy (33).

4.3 Limitations and Strengths of the Study

Limitations of our study could be found in mainly only univariate analysis and less proper comparison of two distant age groups; more data could be additionally analysed with multiple regression. With our study, we gained new insights into population of pregnant adolescents in Slovenia; new knowledge is the strength of this study.

4.4 Implications of the Study Results for Obstetrics and Public Health

The results of our study confirmed that adolescent pregnancy is related to higher health risks for pregnant adolescents and their newborns. Poor prenatal care of adolescents could be improved with better health education and counselling of adolescents in reproductive health (e.g. reproductive cycle, contraception, nutrition, smoking…), in addition to more frequent and intense health and social service given to pregnant adolescents.

4.5 Suggestions for Future Research in the Field

The research on factors of poorer prenatal care in adolescents could be the challenge for future research.

5 CONCLUSIONS

There are differences regarding pregnancy and pregnancy outcomes between adolescents and women aged 20–24 years. These differences should be taken into consideration by health professionals when encountering adolescent pregnant women. Health professionals should intensify prenatal care at first encounter with pregnant adolescents in terms of regular medical check-ups and psychosocial counselling and support.

CONFLICT OF INTEREST

The authors declare that no conflicts of interest exist.

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Oddan rokopis morajo prebrati vsi avtorji in se z njegovo vsebino strinjati.

Raziskave na ljudeh (vključno s človeškimi materiali in osebnimi podatki) morajo biti izpeljane v skladu s Helsinško deklaracijo in potrjene s strani nacionalne etične komisije. V izjavi na koncu rokopisa morajo avtorji podati izjavo o etiki raziskav na ljudeh, ki mora vsebovati ime etične komisije in referenčno številko obravnave. Poročanje o raziskavah na ljudeh brez potrdila etične komisije zahteva dodatno razlago v poglavju o metodah dela. Na zahtevo Uredništva je avtor dolžan predložiti vso dokumentacijo o obravnavi raziskovalne etike njegovega rokopisa. Uredništvo si pridržuje pravico, da kontaktira etično komisijo.

Prav tako morajo avtorji, ki poročajo o ljudeh ali posredujejo javnosti njihovo slikovno gradivo, pridobiti dovoljenja vseh sodelujočih, da se z vključitvijo v raziskavo strinjajo (v primeru otrok so to starši ali skrbniki). Izjavo o pridobitvi teh dovoljenj morajo avtorji podati v poglavju o metodah dela. Uredništvo si pridržuje pravico vpogleda v to dokumentacijo.

Raziskave na živalih morajo biti izpeljane v skladu z navodili “Animal Research: Reporting In Vivo Experiments” (ARRIVE) in potrjene s strani nacionalne etične komisije. V poglavju o metodah dela in v izjavi na koncu rokopisa morajo avtorji podati izjavo o etiki raziskav na živalih z veljavno številko dovoljenja.

V izjavi na koncu rokopisa morajo biti zapisani morebitni finančni ali drugi interesi farmacevtske industrije ali proizvajalcev opreme ter inštitucij, povezani z objavo v ZV/SJPH.

Avtorji morajo na koncu rokopisa zapisati sledeče izjave:

CONFLICTS OF INTEREST (The authors declare that no conflicts of interest exist.)

FUNDING (The study was financed by ...)

ETHICAL APPROVAL (Received from the… ali opis etičnega vidika raziskave)

PLAGIATI

Kadar uredništvo ugotovi, da je rokopis plagiat, se rokopis takoj izloči iz uredniškega postopka. Plagiatorstvo ugotavljamo s programom za odkrivanje plagiatov CrossCheck plagiarism detection system.

ELEKTRONSKA ODDAJA PRISPEVKA

Priporočamo uporabo videoposnetka z navodili za avtorje. Prispevke oddajte v elektronski obliki s pomočjo spletne aplikacije Editorial Manager, ki se nahaja na spletnem naslovu http://www.editorialmanager.com/sjph/. V uredništvo sprejemamo po pošti le še Izjave o avtorstvu in avtorskih pravicah, ki zahtevajo lastnoročni podpis. Prosimo, da jih pošljete hkrati z elektronsko oddajo prispevka na naslov: Nacionalni inštitut za javno zdravje, za revijo Zdravstveno varstvo, Trubarjeva 2, 1000 Ljubljana.

V spletno uredniško aplikacijo se prijavite kot ‘avtor’. Prva prijava zahteva vnos podatkov o avtorju, vse naslednje prijave pa le še vnos podatkov za prijavo, ki jih na svoj elektronski naslov prejmete po prvi prijavi v sistem.

Po uspešni prijavi izpolnite vsa zahtevana strukturirana polja. Potrdite izjavo, da vaš prispevek še ni bil objavljen ali poslan v objavo kakšni drugi reviji, da so prispevek prebrali in se z njim strinjajo vsi avtorji, da so raziskave na ljudeh oz. živalih opravljene v skladu z načeli Helsinško-Tokijske deklaracije oz. v skladu z etičnimi načeli.

Avtorji, ki v objavo pošiljate raziskovalno delo, opravljeno s pomočjo nekega podjetja, to navedite na koncu rokopisa v izjavi o financiranju.

Polje 'Comments' je namenjeno vašim dodatnim razlagam, navedete lahko tudi predlog recenzentov z imeni, nazivi, e-naslovi in zaposlitvijo.

Podatke o avtorju in soavtorjih vnesite kar se da natančno in popolno. Naveden naj bo korespondenčni avtor (s polnim naslovom, telefonsko številko in elektronskim naslovom), ki bo skrbel za komunikacijo z uredništvom in ostalimi avtorji.

Jezik prispevka je angleščina. Objavljamo izvirne znanstvene članke, sistematične pregledne znanstvene članke, metodologije raziskav in vabljene uvodnike. Pri izvirnih, metodoloških in sistematičnih preglednih znanstvenih prispevkih morajo biti naslov, izvleček in ključne besede prevedeni tudi v slovenščino.

Naslov, ključne besede in izvleček se oddajajo dvojezično v angleščini in slovenščini v strukturirana polja. Posebno polje za zapis v drugem jeziku obstaja le za izvleček, preostale podatke vnesite v obeh jezikih v ustrezno isto polje. Prvi izvleček je vselej v angleškem jeziku (do 250 besed - sistem vam besede sproti šteje), drugi pa v slovenskem jeziku (razširjen izvleček - do 400 besed).

Po vnosu strukturiranih podatkov oddajte še priponko - rokopis (od 1 Uvod naprej), ki ne sme zajemati podatkov, ki ste jih vnesli že pred tem v strukturirana polja, zlasti ne podatkov o avtorjih. Ime datoteke ne sme vključevati avtorjevih osebnih podatkov, prav tako ne imen ustanov, vključenih v pripravo rokopisa. Grafično in slikovno gradivo je kot ves rokopis v angleškem jeziku. Vključite ga v besedilo na mesto, kamor le-to sodi in ga opremite z naslovom. Oddate torej le en sam dokument, eno priponko. V Wordu uporabite možnost Postavitev strani/Številke vrstic (tako bo na robu vsake vrstice dokumenta dodana številka vrstice).

Pri oddaji sledite napotkom, ki vam jih ponuja sistem, pomagate pa si lahko tudi z 'Editorial Manager's Tutorial for Autors'.

Sistem najbolje deluje, če uporabljate zadnjo različico Acrobata.

Če pri oddajanju rokopisa naletite na nepremostljive težave, se za pomoč obrnite na naslov uredništva: zdrav.var@nijz.si.

V nadaljevanju podajamo še nekaj natančnejših napotkov.

ROKOPIS

Besedila naj bodo napisana z urejevalnikom Word for Windows 97-2003. Robovi naj bodo široki najmanj 25 mm. Znanstveni članki naj imajo naslednja poglavja: uvod, metode, rezultati, razpravljanje in zaključek. Uvodniki in sistematični pregledni članki so lahko zasnovani drugače, vendar naj bo razdelitev na poglavja in podpoglavja jasno razvidna iz velikosti črk naslovov. Poglavja in podpoglavja naj bodo številčena dekadno po standardu SIST ISO 2145 in SIST ISO 690 (npr. 1, 1.1, 1.1.1 itd.).

DOLŽINA PRISPEVKOV

Zahtevana dolžina prispevka je za vabljen uvodnik od 250 do 1000 besed, za znanstveni članek (originalni, metodološki ali sistematični pregledni) pa od 2000 do 4500 besed s slikovnim gradivom in literaturo vred.

NASLOV IN AVTORSTVO

Naslov v angleškem in slovenskem jeziku naj bo kratek in natančen, opisen in ne trdilen (povedi v naslovih niso dopustne). Navedena naj bodo imena piscev z natančnimi akademskimi in strokovnimi naslovi ter popoln naslov ustanove, inštituta ali klinike, kjer je delo nastalo. Avtorji morajo izpolnjevati pogoje za avtorstvo. Prispevati morajo k zasnovi in oblikovanju oz. analizi in interpretaciji podatkov, rokopis morajo intelektualno zasnovati oz. ga kritično pregledati, strinjati se morajo s končno različico rokopisa. Samo zbiranje podatkov ne zadostuje za avtorstvo.

IZVLEČEK IN KLJUČNE BESEDE

Izvleček v angleškem in slovenskem jeziku naj bo pri znanstvenem in metodološkem članku strukturiran in naj ne bo daljši od 250 besed v angleščini in 400 besed v slovenščini, izvlečki ostalih člankov so lahko nestrukturirani. Izvleček naj vsebinsko povzema in ne le našteva bistvene vsebine dela. Izogibajte se kraticam in okrajšavam. Napisan naj bo v 3. osebi.

Izvleček znanstvenega članka naj povzema namen dela, osnovne metode, glavne izsledke in njihovo statistično pomembnost ter poglavitne sklepe (struktura IMRC - Introduction, Methods, Results, Conclusions).

Navedenih naj bo 3-10 ključnih besed, ki nam bodo v pomoč pri indeksiranju. Uporabljajte izraze iz MeSH - Medical Subject Headings, ki jih navaja Index Medicus.

KATEGORIJA PRISPEVKA

Kategorijo prispevka predlaga z vnosom v ustrezno polje avtor sam, končno odločitev pa sprejme urednik na osnovi predlogov recenzentov. Objavljamo izvirne znanstvene članke, metodološke članke, sistematične pregledne znanstvene članke in vabljene uvodnike.

REFERENCE

Avtorjem priporočamo, da pregledajo objavljene članke na temo svojega rokopisa v predhodnih številkah naše revije (za obdobje zadnjih pet let).

Vsako navajanje trditev ali dognanj drugih morate podpreti z referenco. Reference naj bodo v besedilu navedene po vrstnem redu, tako kot se pojavljajo. Referenca naj bo navedena na koncu citirane trditve. Reference v besedilu, slikah in tabelah navedite v oklepaju z arabskimi številkami ((1), (2, 3), (4-7)). Reference, ki se pojavljajo samo v tabelah ali slikah, naj bodo oštevilčene tako, kot se bodo pojavile v besedilu. Kot referenc ne navajajte izvlečkov in osebnih dogovorov (slednje je lahko navedeno v besedilu). Seznam citirane literature dodajte na koncu prispevka. Literaturo citirajte po priloženih navodilih, ki so v skladu s tistimi, ki jih uporablja ameriška National Library of Medicine v Index Medicus. Uporabljajte numerično citiranje. Imena revij krajšajte tako, kot določa Index Medicus (popoln seznam na naslovu URL: http://www.nlm.nih.gov).

Navedite imena vseh avtorjev, v primeru, da je avtorjev šest ali več, navedite prvih šest avtorjev in dodajte et al.

PRIMERI ZA CITIRANJE LITERATURE

primer za knjigo:

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TABELE

Tabele v angleškem jeziku naj bodo v besedilu prispevka na mestu, kamor sodijo. Tabele naj sestavljajo vrstice in stolpci, ki se sekajo v poljih. Tabele oštevilčite po vrstnem redu, vsaka tabela mora biti citirana v besedilu. Tabela naj bo opremljena s kratkim angleškim naslovom. V legendi naj bodo pojasnjene vse kratice, okrajšave in nestandardne enote, ki se pojavljajo v tabeli.

SLIKE

Slike morajo biti profesionalno izdelane. Pri pripravi slik upoštevajte, da gre za črno-beli tisk. Slikovno gradivo naj bo pripravljeno:

- črno-belo (ne v barvah!);
- brez polnih površin, namesto tega je treba izbrati šrafure (če gre za stolpce, t. i. tortice ali zemljevide);
- v linijskih grafih naj se posamezne linije prav tako ločijo med samo z različnim črtkanjem ali različnim označevanjem (s trikotniki, z zvezdicami...), ne pa z barvo;
- v grafih naj bo ozadje belo (tj. brez ozadja).

Črke, številke ali simboli na sliki morajo biti jasni, enotni in dovolj veliki, da so berljivi tudi na pomanjšani sliki. Ročno ali na pisalni stroj izpisano besedilo v sliki je nedopustno.

Vsaka slika mora biti navedena v besedilu. Besedilo k sliki naj vsebuje naslov slike in potrebno razlago vsebine. Slika naj bo razumljiva tudi brez branja ostalega besedila. Pojasniti morate vse okrajšave v sliki. Uporaba okrajšav v besedilu k sliki je nedopustna. Besedila k slikam naj bodo napisana na mestu pojavljanja v besedilu.

Fotografijam, na katerih se lahko prepozna identiteta bolnika, priložite pisno dovoljenje bolnika.

MERSKE ENOTE

Naj bodo v skladu z mednarodnim sistemom enot (SI).

KRATICE IN OKRAJŠAVE

Kraticam in okrajšavam se izogibajte, izjema so mednarodno veljavne oznake merskih enot. V naslovih in izvlečku naj ne bo kratic. Na mestu, kjer se kratica prvič pojavi v besedilu, naj bo izraz, ki ga nadomešča, polno izpisan, v nadaljnjem besedilu uporabljano kratico navajajte v oklepaju.

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Prispelo gradivo z javnozdravstveno tematiko mednarodnega pomena posreduje uredništvo po tehnični brezhibnosti v strokovno recenzijo trem mednarodno priznanim strokovnjakom. Recenzijski postopek je dvojno slep. Po končanem uredniškem delu vrnemo prispevek korespondenčnemu avtorju, da popravke odobri in upošteva. Popravljen čistopis vrne v uredništvo po spletni aplikaciji Editorial Manager. Sledi jezikovna lektura, katere stroške krije založnik. Med redakcijskim postopkom je zagotovljena tajnost vsebine prispevka. Avtor dobi v pogled tudi prve, t. i. krtačne odtise, vendar na tej stopnji upoštevamo samo še popravke tiskarskih napak. Krtačne odtise je treba vrniti v treh dneh, sicer menimo, da avtor nima pripomb.

V uredništvu se trudimo za čim hitrejši uredniški postopek. Avtorji se morajo držati rokov, ki jih dobijo v dopisih, sicer se lahko zgodi, da bo članek odstranjen iz postopka.

Morebitne pritožbe avtorjev obravnava uredniški odbor revije.

Za objavo članka prenese avtor avtorske pravice na Nacionalni inštitut za javno zdravje kot založnika revije (podpiše Pogodbo o avtorstvu in avtorskih pravicah). Kršenje avtorskih in drugih sorodnih pravic je kaznivo.

Prispevkov ne honoriramo in tudi ne zaračunavamo stroškov uredniškega postopka.

Avtor dobi izvod tiskane revije, v kateri je objavljen njegov članek.